TECHNICAL SPECIFICATIONS OF MEDICAL EQUIPMENT COMMUNITY HEALTH CENTRE

HEALTHACRE TECHNOLOGY DIVISION

NATIONAL HEALTH SYSTEMS RESOURCE CENTRE

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1. FUNDUS CAMERA		
Version no.:		01
Date:		August 2023
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Ophthalmic fundus camera
GMDN code(s)		10551
GENERAL		
1. Use		
1.1	**Clinical purpose**	An electrically powered optical device intended to be used to create digital color photographic images of the ocular fundus (interior eye surface opposite the lens) through the pupil, to aid in diagnosing and monitoring retinal pathology.
1.2	**Used by clinical department/ ward**	Ophthalmology
TECHNICAL		
2. Technical characteristics		
2.1	**Technical characteristics (specific to this type of device)**	1. Both modalities- mydriatic and non-mydriatic imaging should be available. 2. Digital camera should have filter for red, green and blue images with capture sequence of 1.5 to 2 seconds. 3. Should have fluorescent angiography and live visualization features preferably. Should have availability of compensation for ametropia. 4. It should have retinal image montage, HDR & colour and red free imaging facility. 5. Field of View should be at least 45 degrees and above. 6. Camera sensor resolution should be 06 megapixel or more. 7. Should have a focus range of - 15 D to +15D or wider. 8. It should be compatible with Windows PC with facility for image storage in a secondary device such as desktop or a laptop. 9. Supporting computer system with latest

		configuration should be supplied along with the device. 10. Image viewer and archive software should be provided with facility for data storage, data transfer, image archiving and image analysis. 11. It should be DICOM compliant and telemedicine ready.
2.2	**User's interface**	LCD Display for image
2.3	**Software and/or standard of communication (wherever required)**	In built
3. Physical characteristics		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dba)**	N.A.
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Table mounted product
4. Energy source		
4.1	**Power requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	Online UPS system with minimum 30-minute backup.
4.3	**Protection**	NA
4.4	**Power consumption**	As specified by manufacturer
5. Accessories, spare parts, consumables		
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables / reagents (open, closed system)**	1. DVD and CD writer 2. Should be supplied with motorised table and patient stool.
6. Environmental and departmental considerations		
6.1	**Atmosphere / ambiance (air conditioning, humidity, dust ...)**	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%

6.2	**User's care, cleaning, Disinfection & sterility issues**	Easy to clean and maintain.
7. Standards and safety		
7.1	**Certificates (pre-market, sanitary, ..); performance and safety standards (specific to the device type); local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. Training and installation		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. Warranty and maintenance		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. Documentation		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Satisfactory certificate for any existing installation from government hospital
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service support contact details (hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.

11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

2. A SCAN BIOMETER WITH B SCAN		
Version no.:		01
Date:		August 2023
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. Use		
1.1	**Clinical purpose**	A Scan is used to measure the length of the eye for calculation of intra-ocular lens power. B-scan ultrasonography is commonly used to provide a cross sectional image of the internal structure of the eye.
1.2	**Used by clinical department/ ward**	Ophthalmology
TECHNICAL		
2. Technical characteristics		
2.1	**Technical characteristics (specific to this type of device)**	**A Scan Specifications:** 1. 10/11 MHz Biometry probe with applicator and clinical accuracy of +/- 0.1 mm. 2. Ability to measure axial length between 15 and 39 mm. 3. Gain should be 98dB or more with an adjustable range of 0-55dB. 4. Should have measurement memory of 10 per eye. 5. Should have facility for upto five different users to configure the system to their individual settings. 6. Should have five IOL calculations formulas: Holladay, SRK II, SRK T, Binkhorst II,Hoffer Q and an optional Haigis formula. 7. Should have the post refractive K adjustment software for patients who have undergone refractive procedure. 8. Should have the facility for inputs and store White to White data of patients. 9. Should have auto, manual and super auto modes. 10. Should have large 1024 x 600 WSVGA display LED for easy viewing and adjustable screen brightness. 11. Should have age compensation mode for accurate measurements.

		12. Should have programmable velocity for each segment. 13. Should have post-refractive K adjustment software. **B Scan Specification:** 1. Probe frequency should be more than10 MHz. 2. Scanning angle should be minimum 53 deg or better. 3. Resolution: axial equal or less than 0.2 mm and lateral equal or less than 0.4 mm. 4. Total gain should be 98Db or more and adjustable. 5. It should have zoom facility, selectable in 06 steps or more. 6. TGC should be adjustable in 06 point manually. 7. It should have variable delay depth of 0-15 mm. 8. It should have multi-group of electronic callipers for distance measurement. 9. Various area measurement. 10. Post processing: 04 group of curves (linear, logarithmic, exponential, s curve) 11. Gray scale: 256 levels
2.2	**User's interface**	LCD/LED display
2.3	**Software and/or standard of communication (wherever required)**	In built
3. Physical characteristics		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dba)**	N.A.
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
4. Energy source		
4.1	**Power requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	Compatible online UPS with at least 30 minutes backup.
4.3	**Protection**	NA
4.4	**Power consumption**	As specified by manufacturer
5. Accessories, spare parts, consumables		

5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables / reagents (open, closed system)**	Printer roll, dust cover and spare fuses.
6. Environmental and departmental considerations		
6.1	**Atmosphere / ambiance (air conditioning, humidity, dust ...)**	Should be capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%.
6.2	**User's care, cleaning, Disinfection & sterility issues**	Easy to clean and maintain.
7. Standards and safety		
7.1	**Certificates (pre-market, sanitary, ..); performance and safety standards (specific to the device type); local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. Training and installation		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. Warranty and maintenance		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. Documentation		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Satisfactory certificate for any existing installation from government hospital

10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service support contact details (hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations and Warnings**	Any warning sign should be adequately displayed.

3. OPTICAL COHERENCE TOMOGRAPHY (OCT)		
Version no.:		01
Date:		August 2023
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Ophthalmic spectral-domain optical coherence tomography system
GMDN code(s)		58850
GENERAL		
1. Use		
1.1	**Clinical purpose**	Optical Coherence Tomography (OCT) is a non-invasive diagnostic instrument used for imaging the retina.
1.2	**Used by clinical department/ ward**	Ophthalmology
TECHNICAL		
2. Technical characteristics		
2.1	**Technical characteristics (specific to this type of device)**	1. The spectral domain OCT should have confocal Optics and it should be possible to perform both Anterior segment and Posterior segment OCT. 2. The system should have simultaneous Infrared fundus and OCT imaging. 3. The axial resolution of the system should be 03 microns and transverse resolution 12 microns or better. 4. The OCT system should have real time eye tracking facility for precise alignment of blood vessels from fundus image to the corresponding OCT scan and minimize internal eye motion related artifacts. 5. Should have eye tracking while taking single line scan as well as high density volume scan. 6. Should have a field of view 30 deg or better. 7. The system should have Enhanced depth imaging to view Choroidal layer. 8. It should be possible to perform volume section scan for detailed analysis of lesions. 9. The system should have Retinal Nerve fibre layer thickness analysis and posterior pole asymmetry

		analysis for Glaucoma assessment. 10. The OCT system should have in-built segmentation software for delineation of layers of retina, (Nerve Fibre Layer) NFL or Retinal pigment epithelium (RPE). 11. It should be possible to view irido corneal angles of either side. 12. It should be possible measure corneal thickness in the anterior segment OCT mode.
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication(wherever required)**	In built
3. Physical characteristics		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dba)**	N.A.
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
4. Energy source		
4.1	**Power requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	Online UPS with minimum one-hour back-up.
4.3	**Protection**	NA
4.4	**Power consumption**	As specified by manufacturer.
5. Accessories, spare parts, consumables		
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables / reagents (open, closed system)**	PC Networking
6. Environmental and departmental considerations		
6.1	**Atmosphere / ambiance (air conditioning, humidity, dust ...)**	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User's care, cleaning, Disinfection & sterility issues**	Easy to clean and maintain

7. Standards and safety		
7.1	**Certificates (pre-market, sanitary, ..); performance and safety standards (specific to the device type); local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. Training and installation		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. Warranty and maintenance		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. Documentation		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Satisfactory certificate for any existing installation from government hospital
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service support contact details (hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

4. BLOOD WARMER		
Version no.:		01
Date:		August 2023
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. Use		
1.1	**Clinical purpose**	A blood warmer is used to warm blood or other fluids, minimizing the risk of hypothermia.
1.2	**Used by clinical department/ ward**	Emergency, ICU
TECHNICAL		
2. Technical characteristics		
2.1	**Technical characteristics (specific to this type of device)**	1. Should be able to warm blood at a temperature range of 37˚C – 40˚C with control knob. 2. Should be able to maintain or warm blood/fluid at a flow rate of 2.5 L/min. 3. It should have digital temperature display of fluid. 4. Should use inbuilt water tank /dry heat technology / counter current heat exchanger technology to warm the infused fluid/blood. 5. Should be able to attach to IV set. 6. Should have a digital display of temperature. 7. Audio visual alarms for disconnections and over temperature must be present. 8. Should be compatible for both adult and Paediatric patients.
2.3	**User's interface**	NA
2.4	**Software and/or standard of communication (wherever required)**	NA
3. Physical characteristics		
3.1	**Dimensions (metric)**	NA

3.2	**Weight (lbs, kg)**	Light weight
3.3	**Noise (in dba)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
	4. Energy source	
4.1	**Power requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.4	**Power consumption**	As specified by manufacturer
	5. Accessories, spare parts, consumables	
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables / reagents (open, closed system)**	At least 80 disposable tubing set for adults and 20 for paediatrics should be supplied.
	6. Environmental and departmental considerations	
6.1	**Atmosphere / ambiance (air conditioning, humidity, dust ...)**	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User's care, cleaning, Disinfection & sterility issues**	Easy to clean and maintain
	7. Standards and safety	
7.1	**Certificates (pre-market, sanitary, ..); performance and safety standards (specific to the device type); local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards in case of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
	8. Training and installation	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over

8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. Warranty and maintenance		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. Documentation		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Satisfactory certificate for any existing installation from government hospital
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service support contact details (hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations and Warnings**	Any warning sign should be adequately displayed.

5. HYSTEROSCOPY SET		
Version no.:		01
Date:		August 2023
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. Use		
1.1	**Clinical purpose**	Hysteroscopy is a procedure to examine the inside of the uterus. Hysteroscope is used for this process which is a narrow telescope with light and camera at the end.
1.2	**Used by clinical department/ ward**	Gynaecology Department
TECHNICAL		
2. Technical characteristics		
2.1	**Technical characteristics (specific to this type of device)**	**Hysteroscopy set should consist of following:** • CCD camera system. • Resectoscope • Monitor • Light Source with Light Guide Cable • Fluid Management System • Mobile Trolley **1. Hysteroscopy set with accessories:** • Hysteroscope Forward-Oblique Telescope 30° (Diameter more than 2 mm). • Diagnostic sheath must not exceed 3mm when assembled for continuous flow • Therapeutic sheath should not exceed 4.5 mm when assembled for continuous flow with 5 fr (French Gauge- 1 fr = 0.33 mm) working channel • Semi- rigid 5 Fr biopsy forceps and Semi-rigid 5 Fr grasping forceps for removing IUCDs • System should be Autoclavable.

		• Dedicated protection tube for telescope should be available. **2. Resectoscope:** Connecting tube for inflow and outflow for the above 4 mm hysteroscope telescope complete with continuous irrigation double sheath system, i.e outer flow and rotating inner tube with ceramic insulation distal tip complete set of electrodes and 2 set of HF cables. **3. CCD High Resolution Camera System:** **Camera Head:** • Should be waterproof with a high resolution interline rugged CCD system and compatible with Fiber optic endoscope. • High Quality Image by 10 Bit DSP (Digital Signal Processor) • Signal Noise — 50 dB or less • Brightness — 1.8 (3 Lux) or more **Camera Control Unit:** • Auto Gain Control • White Balance — Automatically adjusted by the Button • Should have facility for Brightness Control **4.Monitor:** • Should be supplied with 15 inch or more medical grade Monitor. • It should have USB port for capturing videos and stills in external USB drive. **5. Light Source with Light Guide Cable:** • LED light source suitable for performing Hysteroscopy. • Light Guide Cable. **6. Fluid Management System:** • The pump must be indicated to provide liquid distension of the uterus during diagnostic and operative hysteroscopy. The volume differential between the irrigation fluid flowing into and out of the uterus must be monitored. • The pump must be electronically pressure controlled

		• Nominal pressure must be able to preset between 10 and 160 mmHg. • Flow must be able to maintain between 0 and 500 ml/min. • Intrauterine pressure must be maintained and displayed as well as the pre-set pressure and flowrate. • Intrauterine pressure must be displayed as well by large numeric as symbolic. • Overpressure must be displayed visually and by acoustic and rapid deficit alarm. • The graphic user interface of the pump should be a touchscreen/Digitally controlled. • Device should operate with a completely non-contact pressure measurement of the irrigation-medium due to closed system. • Patient safety must be given by accurate pressure monitoring and several alarms. • Tubing set must be able to set-up two irrigation bags and must have either inflow and outflow tubing or inflow tubing only. • Tubing set for inflow only must be re-usable and must not exceed 20 autoclave cycles • Tubing set coming with inflow and outflow tubing should be DEHP-free and single-use. **7. CO2 Electronic Insufflator 30L/M and above flow rate:** 1. Electronic CO2 insufflators with pin index connection 2. Should have an adjustable flow rate of 0 to 30 ltr. per minute or above and a pressure range adjustable between 0-30 mm Hg. 3. Preset and actual value for Pressure and flow should be displayed together on the front panel in digital display. 4. Constant monitoring of intra-abdominal pressure; any overpressure is released immediately with back flow with acoustic alarm. 5. Unit should have in-built heater to warm up and preheat the CO2 gas. 6. Should be able to select either central supply (4.5Kg/cm2) input pressure from central supply as well as

		direct connection to high pressure CO2 cylinder and should indicate the right inlet pressure of CO2 gas supply by bar graph on front panel of machine. 7. Unit should produce immediately acoustic alarm in case of sudden blockage in the gas outlet tube or wrongly placed Veress Needle. 8. Provided with Silicon autoclave tubing with luer attachment. 9. Should have internal heater to initially heat the CO2 gas to a level to make it from liquid to gas. 10. Should have external integrated heater to deliver CO2 gas at body temperature. **8. Mobile Trolley:** • A mobile trolley to accommodate all the items to be used for performing Office Hysteroscopy. • Should be having strong wheels.
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication (wherever required)**	NA
3. Physical characteristics		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dba)**	N.A.
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
4. Energy source (electricity, Ups, solar, gas, water, co2)		
4.1	**Power requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.4	**Power consumption**	As specified by manufacturer
5. Accessories, spare parts, consumables		

5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables / reagents (open, closed system)**	NA
6. Environmental and departmental considerations		
6.1	**Atmosphere / ambiance (air conditioning, humidity, dust ...)**	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User's care, cleaning, Disinfection & sterility issues**	To be specified by manufacturer.
7. Standards and safety		
7.1	**Certificates (pre-market, sanitary, ..); performance and safety standards (specific to the device type); local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. Training and installation		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. Warranty and maintenance		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter
10. Documentation		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams.

		2. Service and operation manuals (original and Copy) to be provided. 3. Satisfactory certificate for any existing installation from government hospital
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service support contact details (hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations and Warnings**	Any warning sign should be adequately displayed.

6. Manual Vacuum Aspirator		
Version no. :		01
Date:		August 2023
Done by : (Name/Institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	Clinical purpose	A non-sterile, manual, syringe-like device intended to be used in conjunction with an intrauterine cannula (not included) to aspirate fluid from the uterus for treatment of incomplete abortion, first trimester abortion, and/or for menstrual regulation; it may also be intended for endometrial biopsy.
1.2	Used by clinical department/ward	Gynecology
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. It should be double valve type manually operated vacuum aspirator. 2. Valve should have double locking system. 3. It should have 60 ml calibrated barrel and plunger cum piston rod with ergonomic handle to withstand autoclave at 120 deg C and more. 4. Vacuum capacity should be above 650 mm/hg. 5. Cannula adapter size should be from 4mm-12mm.
2.2	User's interface	Manual
2.3	Software and/or standard of communication (where ever required	Not required
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA

3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Collar stop clip
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	As specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA

8.3	Training of staff (medical, paramedical, technicians)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	NA
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	One copy (hard copy and soft copy) to be provided on user manual/ operating manual.
10.2	Other accompanying documents	NA
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier should be provided
11.2	Recommendations or warnings	NA

7. Shoulder Wheel		
Version no. :		01
Date:		August 2023
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		-
GMDNS code(s)		-
GENERAL		
1. USE		
1.1	Clinical purpose	The wheel allows carrying out a shoulder exercise safely and decrease the pain in shoulder and arms
1.2	Used by clinical department/ward	Physiotherapy
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. The shoulder wheel is a metal drum fitted with adjustable bars made of Stainless Steel. 2. The wheel should be wall mounted. 3. Adjustment bar to raise up and release down as per the height requirements fitted on a laminated board frame. 4. The wheel should provide smooth 360-degree revolution bidirectionally.
2.2	User's interface	Manual
2.3	Software and/or standard of communication (wherever required	Not required
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	Diameter- 50 cm or more
3.2	Weight (lbs, kg)	Not more than 10 kg
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Fixed

4. ENERGY SOURCE		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Not required.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance(air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	Should be easy to clean and maintain.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,); Performanceand safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover
8.3	Training of staff (medical, paramedical, technicians)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	03 years
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams.

10.2	Other accompanying documents	NA
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer and supplier to be provided.
11.2	Recommendations or warnings	NA

8. Shoulder Pulley		
Version no. :		01
Date:		August 2023
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		-
GMDNS code(s)		-
GENERAL		
1. USE		
1.1	Clinical purpose	Shoulder pulleys help to stretch the shoulder in various directions to improve mobility and function of the shoulders.
1.2	Used by clinical department/ward	Physiotherapy
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Wall mountable unit and the set should include mounting hardware. 2. Construction: Tubular stainless-steel tube is fitted with two close hooks to fix pulleys. 3. Pulleys: Two, Nylon pulleys with hooks to fix. 4. Grip Handles: Two, spring steel wire handles with grips. 5. Rope/Cord: Durable interwoven Nylon cord of suitable length.
2.2	User's interface	Manual
2.3	Software and/or standard of communication (wherever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA

3.4	Heat dissipation	NA
3.5	Mobility, portability	Fixed
4. ENERGY SOURCE		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Not required.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance(air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	Should be easy to clean.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,); Performanceand safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	NA
10. DOCUMENTATION		

10.1	Operating manuals, set manuals, other manuals	NA
10.2	Other accompanying documents	NA
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer to be provided.
11.2	Recommendations orwarnings	NA

9. Shoulder Abduction Ladder/Wall Ladder Finger Exerciser		
Version no. :		01
Date:		August 2023
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		-
GMDNS code(s)		-
GENERAL		
1. USE		
1.1	Clinical purpose	It is used to offer progressive motion exercises for the shoulder, elbow and wrist joints of the patients.
1.2	Used by clinical department/ward	Physiotherapy
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Wall mounted ladder used for shoulder/finger exercise. 2. Should be made up of polished wood/high quality fiber plastic. 3. The ladder should have minimum 30 steps. 4. Height of the step: 36-38 mm. 5. Each step should be numbered to give feed-back to the patient and to keep record of progress.
2.2	User's interface	Manual
2.3	Software and/or standard of communication (wherever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA

3.5	Mobility, portability	Fixed
4. ENERGY SOURCE		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Not required.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance(air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	Should be easy to clean.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,); Performanceand safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards in case of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	NA
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	NA

10.2	Other accompanying documents	NA
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer to be provided.
11.2	Recommendations or warnings	NA

10. Nd YAG Laser		
Version no.:		01
Date:		August 2023
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. Use		
1.1	**Clinical purpose**	Nd YAG lasers are most commonly used to treat posterior capsular opacification (PCO) after cataract surgery and to create a peripheral iridotomy in patients with narrow angles or angle-closure glaucoma
1.2	**Used by clinical department/ ward**	Eye OT
TECHNICAL		
2. Technical characteristics		
2.1	**Technical characteristics (specific to this type of device)**	1. Laser Type: Neodymium Yttrium Aluminium Garnet 2. Should have Wavelength of 1064 nm. 3. Should have following mode of Operation: Q-Switched (CQ-Crystal) 4. Energy Output: Maximum of 45 mJ in Triple pulse mode. Nominally 1 mJ maximum in single pulse mode 5. Energy Adjustment: Continuously variable across full energy range 6. Burst Mode: 1.2 or 3 pulse each burst with the separation between pulses of 20 ms 7. YAG Offset Focus: Continuously variable from Anterior (-) 500 um to Posterior (+) 500um. In steps of 0, +/-150, 250, 500 um 8. Pulse width: 4ns +/- 2ns 9. Repetition Rate: 2.5Hz for single pulse 10. Spot Size: 8µm-10µ 11. Cone Angle: 160 12. Focal length: 107mm 13. Energy Display accuracy: Better than+/-20% of actual 14. Aiming Beam:630-670nm (Red) laser Diode, 4 Point 15. Mode of Operation: Continuous wave (CW) 16. Should have monocular assistant eye piece.
2.3	**User's interface**	Manual

2.4	**Software and/or standard of communication (wherever required)**	NA
	3. Physical Characteristics	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dba)**	N.A.
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Tabletop
	4. Energy source	
4.1	**Power requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	UPS: with at least 30 minutes battery back up
4.3	**Protection**	NA
4.4	**Power consumption**	As specified by manufacturer
	5. Accessories, spare parts, consumables	
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables / reagents (open, closed system)**	1. Should be supplied with slit lamp (5 step magnification 5, 8, 12, 20 , 32x) 2. Eye piece of at least 10X/12.5X to be supplied. 3. Should be supplied with motorised table. 4. Should provide protective goggles for Nd-Yag Laser 5. Should provide contact lens for iridotomy and capsulotomy.
	6. Environmental and departmental considerations	
6.1	**Atmosphere / ambiance (air conditioning, humidity, dust ...)**	Should be capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User's care, cleaning, Disinfection & sterility issues**	To be specified by manufacturer.
	7. Standards and safety	
7.1	**Certificates (pre-market, sanitary, ..); performance and safety standards (specific to**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.

	the device type); local and/or international	5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. Training and installation		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. Warranty and maintenance		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter
10. Documentation		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Satisfactory certificate for any existing installation from government hospital
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service support contact details (hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations and Warnings**	Any warning sign should be adequately displayed.

11. NCV- EMG VEP MACHINE (Nerve Conduction Velocity, electromyograph, Visual Evoked Potential Machine)		
Version no.:		01
Date:		August 2023
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. Use		
1.1	**Clinical purpose**	It detects, process, and records electrical activity of nerves, neuromuscular junctions and skeletal muscles. Evoked Potential graphic recorders measure and document the brain's electrical response to visual, auditory, or somatosensory stimuli.
1.2	**Used by clinical department/ ward**	Physical Medicine and Rehabilitation Unit
TECHNICAL		
2. Technical characteristics		
2.1	**Technical characteristics (specific to this type of device)**	1. NCV-EMG EP machine should have at least 4 Channels or more. 2. NCV-EMG EP machine should be based on Windows Operating System, Desktop Computer/laptop with latest configuration and high storage capacity. 3. Amplifiers should have at least 4 Optically Isolated Channels with 14/16/24-bit ADC, CMRR should be more than 100dB, Input Impedance should be more than 100M Ohms, Sensitivity from 1 microV/Div to 20 mV/Div and should have sweep speed in the range of 1 to 1000 ms /div . 4. System should have handheld electrical Stimulator with stimulus intensity dial and stimulus trigger on handle. 5. It should have start /stop switches provided on handle. It should stimulate with constant Electrical Current (from 0 to 100mA) up to 1 ms duration. It should be electrically isolated with independent controls. 6. The system should have the following Application software as standard :- • Motor and Sensory nerve conduction, F -wave, H-reflex, Blink

		reflex, Repetitive nerve stimulation test, inching. • It should have packages for doing EMG acquisition and analysis, advanced quantitative analysis of EMG (facility to record/Replay EMG on Hard Drive).On single screen surface EMG, SP activity , interference pattern , single motor unit potential , turn/amplitude analysis should be possible. Manual/auto MUPs selection for analysis • Somatosensory SEP, ABR, Pattern Reversal VEP, LED Goggles VEP, P-300 etc. 7. The system should have facility for Automatic Online Summary Report
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication (wherever required)**	In-built
3. Physical characteristics		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dba)**	N.A.
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
4. Energy source		
4.1	**Power requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	Rechargeable battery with minimum 24 hours backup
4.3	**Protection**	NA
4.5	**Power consumption**	As specified by manufacturer
5. Accessories, spare parts, consumables		
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)**	NA

	Consumables / reagents (open, closed system)	
6. Environmental and departmental considerations		
6.1	**Atmosphere / ambiance (air conditioning, humidity, dust ...)**	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User's care, cleaning, Disinfection & sterility issues**	To be specified by manufacturer.
7. Standards and safety		
7.1	**Certificates (pre-market, sanitary, ..); performance and safety standards (specific to the device type); local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. Training and installation		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. Warranty and maintenance		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter
10. Documentation		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided.

		3. Satisfactory certificate for any existing installation from government hospital
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service support contact details (hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations and Warnings**	Any warning sign should be adequately displayed.

12. CTG Machine		
Version no.:		01
Date:		August 2023
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. Use		
1.1	**Clinical purpose**	For recording and analysing the Fetal Heart Rate (FHR) and contractions of uterus during antepartum and intrapartum period.
1.2	**Used by clinical department/ ward**	Obs & Gynaecology OPD & OT, LDR Complex
TECHNICAL		
2. Technical characteristics		
2.1	**Technical characteristics (specific to this type of device)**	1. LCD Screen for Foetal Heart Rate, Uterine Contractions & Foetal Movement. 2. LCD Screen should be tiltable, rotatable and can be fixed at any angle from 0-90 degree 3. It should have display modes of Trend mode, Number mode & Graph Mode. 4. It should have alarm functions in all movement with facility to adjust alarm sounds. 5. It should have Automatic track & hold facility. 6. The probe should be highly sensitive to pick up FHR and waterproof within the range of 2 to 5 MHz frequency. 8. It should have Foetal Heart Rate & Uterine Pressure recording system. 9. It should have automatic & manual foetal movement detection. 10. It should have inbuilt thermal recorder. 11. It should have Twin Foetal Monitoring system (Capability to pick up the FHR of the twins separately).
2.2	**User's interface**	Manual

2.3	**Software and/or standard of communication (wherever required)**	In-built
3. Physical characteristics		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dba)**	N.A.
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
4. Energy source (electricity, Ups, solar, gas, water, co2)		
4.1	**Power requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	Battery with minimum 1 hr backup.
4.3	**Protection**	NA
4.5	**Power consumption**	As specified by manufacturer
5. Accessories, spare parts, consumables		
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables / reagents (open, closed system)**	• US probe/FHR probe - 2 nos. • Toco Probe - 1 no. • Print paper - 10 rolls • Power adapter & Cord - 1 no. • Ultrasound Gel - 4 no. • Probe Belt - 3 sets
6. Environmental and departmental considerations		
6.1	**Atmosphere / ambiance (air conditioning, humidity, dust ...)**	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User's care, cleaning, Disinfection & sterility issues**	To be specified by manufacturer.
7. Standards and safety		

7.1	**Certificates (pre-market, sanitary, ..); performance and safety standards (specific to the device type); local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. Training and installation		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. Warranty and maintenance		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. Documentation		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Satisfactory certificate for any existing installation from government hospital
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service support contact details (hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.

11.2	**Recommendations and Warnings**	Any warning sign should be adequately displayed.

13. INFANTOMETER		
Version no. :		01
Date:		August 2023
Done by : (name. Institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	Clinical purpose	An Infantometer is used to measure an infant's length from heel to head
1.2	Used by clinical department/ward	Neonatal Intensive Care Unit (NICU)
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. The Infantometer should be compact and light weight. 2. It should have graduation in both mm and cm. 3. It should be made of good-quality, skin friendly, durable material. 4. Should be foldable for easy carrying and space saving. 5. Should have integrated head positioner and easy to move leg positioner. 6. Should have smooth, rounded surfaces to prevent bumps and jolts during measuring and make cleaning easy. 7. Measuring Range should be upto 100 cm or more.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	In accordance with measuring range mentioned in technical characteristics.
3.2	Weight (lbs, kg)	Light weight
3.3	Noise (in dBA)	NA

3.4	Heat dissipation	NA
3.5	Mobility, portability	Portable
4. ENERGY SOURCE		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	Durable resistant to effects of excess humidity and high temperature.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Should be easily disinfected by using normal hospital grade cleaning solution.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE Standards in case of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	03 Years

10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: User manuals should be supplied in English/Hindi language along with machine diagrams.
10.2	Other accompanying documents	NA
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer and supplier to be provided.
11.2	Recommendations or warnings	NA

14. STADIOMETER		
Version no.:		01
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	**Clinical purpose**	A stadiometer is a device used to measure body height in vertical position.
1.2	**Used by clinical department/ward**	OPD
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Should have adjustable measuring range to accommodate tall person (minimum 200 cm) with graduation marks on either side in cm/mm and inches/ft metrics. 2. It should be light weight, portable with a sturdy base capable to accommodate weight upto 200 Kg. 3. It should be made of high-quality material stainless steel (SS-304)/wood or moulded unbreakable plastic/Fibre material with an adjustable head rod. 4. Should be portable, light weight and easy to carry. 5. Durable resistant to effects of excess humidity and high temperature and water resistant.
2.2	**User's interface**	Manual
2.3	**Software and/ or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	In accordance with measuring length mentioned in technical characteristics

3.2	**Weight (lbs, kg)**	Light weight
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE		
4.1	**Power requirements**	NA
4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.4	**Power consumption**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Should be supplied with carry bag or carry case
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Durable resistant to effects of excess humidity and high temperature.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Should be easily disinfected by using normal hospital grade cleaning solution.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards in case of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	NA
9. WARRANTY AND MAINTENANCE		

9.1	**Warranty**	3 years
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: • User, technical and maintenance manuals in English/Hindi language along with machine diagrams;
10.2	**Other accompanying documents**	NA
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer and supplier should be provided.
11.2	**Recommendations or warnings**	NA

15. Spirometer		
Version no.:		01
Date:		August 2023
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. Use		
1.1	**Clinical purpose**	A spirometer is an apparatus for measuring the volume of air inspired and expired by the lungs.
1.2	**Used by clinical department/ ward**	Anaesthesia Department
TECHNICAL		
2. Technical characteristics		
2.1	**Technical characteristics (specific to this type of device)**	1. The spirometer should be portable and should have facility to interface for desktop / Laptop Computer. 2. The microprocessor/computer should be capable of accepting patient identification number (i.e age, height, gender and date). 3. It should be able to monitor the following parameters: • Spirometry & Flow Volume Parameter • Maximum Ventilation Volume • Pre & Post Bronchodilator comparison • Lung Volumes & Sub – divisions • Broncho Provocation Test. 4. Flow meter: –Bi-directional digital turbine or Pneumotach. 5. Should incorporate Electronic Barometer & temperature Sensors, for Automatic BTPS Correction. 6. The device should provide real time flow volume and volume – time traces on computer/microprocessor screen.
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication**	In-built

	(wherever required)	
3. Physical characteristics		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dba)**	N.A.
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
4. Energy source (electricity, Ups, solar, gas, water, co2)		
4.1	**Power requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	UPS with power backup of at least 30 minutes
4.3	**Protection**	NA
4.5	**Power consumption**	As specified by manufacturer
5. Accessories, spare parts, consumables		
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables / reagents (open, closed system)**	1. Computer interfacing package, cables and software 2. Disposable mouth pieces-100
6. Environmental and departmental considerations		
6.1	**Atmosphere / ambiance (air conditioning, humidity, dust ...)**	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User's care, cleaning, Disinfection & sterility issues**	To be specified by manufacturer.
7. Standards and safety		
7.1	**Certificates (pre-market, sanitary, ..); performance and safety standards (specific to the**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.

	device type); local and/or international	5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. Training and installation		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. Warranty and maintenance		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. Documentation		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Satisfactory certificate for any existing installation from government hospital
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service support contact details (hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations and Warnings**	Any warning sign should be adequately displayed.

16. Mechanical Ventilator (ICU)		
Version no.:		01
Date:		August 2023
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. Use		
1.1	**Clinical purpose**	Mechanical ventilators are life support devices that move gas (e.g., air and/or oxygen) to and from a patient's lungs. These devices may provide temporary or permanent respiration for patients who cannot breathe on their own, or who require assistance maintaining adequate ventilation. It can be used in two modes Invasive (Tube Inside trachea) and Non invasive (through face mask/nasal tube) ventilation.
1.2	**Used by clinical department/ ward**	ICU
TECHNICAL		
2. Technical characteristics		
2.1	**Technical characteristics (specific to this type of device)**	1. Should have facility for Invasive and Non-Invasive ventilation. 2. Microprocessor Control suitable for Pediatric and adult ventilation. 3. Electromagnetic Compatible Hinged arm holder for holding the circuit. 4. Should have built in touch colour screen TFT display of minimum 10" or more for display of waveforms and Monitored value. 5. Should have inbuilt facility to upgrade with EtcO2. 6. **Facility to Measure and display: -** a) Status indicator for ventilator mode. b) Battery indication. c) Pressure Vs time Vs volume Vs time, flow Vs time 3 curves/ waveforms. d) Alarm setting. 7. Automatic compliance and leakage compensation for circuit and ET Tube. 8. Should have facility of logbook, for events and alarms with date &

		time. 9. **Should have following settings.** a) Tidal volume (Minimum at least 50ml, Maximum up to 2000ml) b) Inspiratory Pressure (upto 80 cm of H20) c) Respiratory rate 1 to 80 bpm. d) Apnoea back up rate. e) CPAP/PEEP f) Pressure support. g) Fi02 h) Pause Time i) Pressure & flow Trigger j) Inspiratory flow up to 120 Lpm. 10. **Monitoring and Display of the following Parameters.** a) Airway Pressure (Peak & Mean). b) Tidal volume (Inspired & Expired). c) Minute volume (Inspired & Expired d) Respiratory mechanics. e) Spontaneous Minute Volume. f) Total Frequency. g) F102 dynamic. h) Intrinsic PEEP. i) Plateau Pressure. j) Resistance & Compliance. k) Use selector Alarms for all measured & monitored parameters. l) Occlusion Pressure. m) Pressure Flow & Volume curves. 11. **Modes of Ventilation equipped with newer modes of ventilation: -** a) Assist /control. b) Volume Control. c) Pressure control. d) Pressure support. e) SIMV with pressure support (Pressure and volume control). f) PEEP. g) Inverse ratio Ventilation. h) Non-invasive ventilator- BIPAP, CPAP. i) Apnea Ventilation, User selectable, volume & pressure control.

		12. Should have built in safety alarms for Airway Pressure High & low, Minute volume, High & low, power failure, Low oxygen, High Respiratory Rate, Air Source in-operable. 13. Should have inbuilt exhalation filter. 14. Compressor should be of same company inbuilt/ mounted with ventilator assembly. 15. Should have compatibility with existing central pipe line. 16. **Humidifier** a) Servo controlled heated Respiratory Humidifier. b) Temperature of delivered Gas on LED display. c) Temperature should be adjustable. d) Jar should be autoclavable 17. Nebulization assembly compatible with ventilator and circuit. 18. Should have interface facility. 19. Flow Sensor-Should have life more than 1 year. 20. Expiratory Unit- Life should be more than 3yrs. 21. Data storage facility for at least 24hrs. 22. Internal rechargeable battery at least 30min. backup. 23. Should be supplied with compatible UPS.
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication (wherever required)**	In-built
3. Physical characteristics		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dba)**	N.A.
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Mobile
4. Energy source (electricity, Ups, solar, gas, water, co2)		
4.1	**Power requirements**	220 +/- 10% VAC, 50 Hz

4.2	**Battery operated**	Battery backup of atleast one hour.
4.3	**Protection**	NA
4.5	**Power consumption**	As specified by manufacturer
	5. Accessories, spare parts, consumables	
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables / reagents (open, closed system)**	a) Patient breathing circuit of silicone for Adult & Paediatric (reusable). b) Non-invasive ventilator mask reusable for adult (3sizes) and paediatric according to age- 4 set each. c) ET tube cuff pressure monitor and HME filter - 10.
	6. Environmental and departmental considerations	
6.1	**Atmosphere / ambiance (air conditioning, humidity, dust ...)**	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User's care, cleaning, Disinfection & sterility issues**	To be specified by manufacturer
	7. Standards and safety	
7.1	**Certificates (pre-market, sanitary, ..); performance and safety standards (specific to the device type); local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
	8. Training and installation	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over
8.3	**Training of staff (medical,**	Training of users in operation and basic maintenance shall be provided.

	paramedical, technicians)	
9. Warranty and maintenance		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter
10. Documentation		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Satisfactory certificate for any existing installation from government hospital
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service support contact details (hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations and Warnings**	Any warning sign should be adequately displayed.

17. Washer Disinfector		
Version no.:		01
Date:		August 2023
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. Use		
1.1	**Clinical purpose**	A washer disinfector is used for the automated cleaning and disinfection of instruments in practices.
1.2	**Used by clinical department/ ward**	Operation Theatre
TECHNICAL		
2. Technical characteristics		
2.1	**Technical characteristics (specific to this type of device)**	1. Should have minimum capacity of 45 ltrs. 2. Washer Disinfector, single door, suitable for cleaning and disinfection of surgical instruments, anaesthetic equipment, suction bottles, general circulation goods, dental tray and glassware with a fully closed process. 3. The washer disinfector, fully automatic, should have an advanced micro-processor which controls all services, programming and static functions. For safety reasons the service and programming functions should be coded. 4. The door should be provided with interlocking system. The chamber should be equipped with minimum four spray arms which ensure good water penetration from all directions. 5. Various attachments should be provided to suit the load to be washed. Suitable dosage of detergent to be preset with the dosing pump. 6. The wash chamber, the inside door, the pipework system and the circulation arms should be made up of stainless steel.
2.2	**User's interface**	Automatic
2.3	**Software and/or standard of communication**	NA

	(wherever required)	
3. Physical characteristics		
3.1	**Dimensions (metric)**	Chamber dimension should suit the capacity.
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dba)**	The provision of a double wall with insulation in between enables the Washer Disinfector to run with minimum sound and heat emission.
3.4	**Heat dissipation**	The provision of a double wall with insulation in between enables the Washer Disinfector to run with minimum sound and heat emission.
3.5	**Mobility, portability**	NA
4. Energy source (electricity, Ups, solar, gas, water, co2)		
4.1	**Power requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.5	**Power consumption**	As specified by manufacturer
5. Accessories, spare parts, consumables		
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables / reagents (open, closed system)**	Consumables equivalent for 100 cycles.
6. Environmental and departmental considerations		
6.1	**Atmosphere / ambiance (air conditioning, humidity, dust ...)**	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User's care, cleaning, Disinfection & sterility issues**	To be specified by manufacturer
7. Standards and safety		
7.1	**Certificates (pre-market, sanitary, ..);**	1. Should be CDSCO approved. 2. Should comply with BIS standards.

	performance and safety standards (specific to the device type); local and/or international	3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. Training and installation		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. Warranty and maintenance		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter
10. Documentation		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Satisfactory certificate for any existing installation from government hospital
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service support contact details (hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations and Warnings**	Any warning sign should be adequately displayed.

18. DIGITAL THERMOMETER		
Version no.:		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Intermittent Electronic Patient Thermometer
GMDN code(s)		14035
GENERAL		
1. USE		
Clinical Purpose		A hand-held non-mercury digital thermometer (battery-powered, electronic instrument) is used to measure a patient's body temperature.
Used by Clinical department/ ward		All Clinical Departments
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	• Range of temperature measurement 32 deg C- 42 deg C (89.60F-109.40F). • Accuracy of temperature ± 0.1degC or ± 0.2 F. • Should have digital display with temperature showing in both Centigrade and Fahrenheit interchangeable mode using a button. • Beep sound when final steady temperature arrived during test. • Buzzer alert function for indicating low (< 35 deg C /95 deg F) for hypothermia and high (> 42 deg C/ 106 deg F) temperature for hyperthermia. • Takes 60-90 seconds to measure temperature. • Can be used in the armpit/axilla, orally and rectally. • Should have auto shut down feature for remaining idle for more than 1 minute.
2.2	**User's interface**	Digital display
2.3	**Software and/or standard of communication**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**heat dissipation**	NA
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	**Power Requirements**	NA

4.2	**Battery operated**	Yes
4.3	**Protection**	NA
4.4	**Power consumption**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional) Spare parts (main ones) Consumables/reagents (open, closed system)**	Batteries
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of operating in ambient temperature of -10 to 60 deg C and relative humidity of upto 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	• Should be CDSCO approved. • Should comply with BIS standards. • Should comply with USFDA/European CE standards in case of non-availability of BIS standards. • Should conform to ISO 13485 quality standards.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	NA
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	03 years
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	User manual along with machine diagram should be provided.
10.2	**Other accompanying documents**	NA
	11. NOTES	
11.1	**Service support contact details (hierchy Wise;**	Contact details of manufacturer should be provided.

	including a toll free/landline number)	
11.2	**Recommendations or Warnings**	NA

19. STETHOSCOPE		
Version no.:		02
Date:		August 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Mechanical Stethoscope
GMDN code(s)		13755
GENERAL		
1. USE		
1.1	**Clinical purpose**	It is used for listening to sounds from the heart, lungs, and/or gastrointestinal tract. It typically comprises a membrane at the listening head connected by a split "Y" tube to the headgear with ear olives that are placed into the users' ears.
1.2	**Used by clinical department/ward**	All Departments
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Should have single lumen binaural. 2. Latex free Polyvinyl chloride (PVC) stethoscope tubing, soft and should not harden/crack. 3. Tube should be impervious to outside noises. 4. Earpieces (02) should be with soft sealing ear tips and easy to stay fixed in ears. 5. Earpiece material: Soft PVC/Silicone preferably. 6. Should have good quality and highly sensitive fixed/floating diaphragm. 7. Dual head: Cup/ bell for low frequency sounds, sensitive membrane for skin contact.
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		

3.1	**Dimensions (metric)**	Tube length – 55 cm minimum
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**heat dissipation**	NA
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.4	**Power consumption**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories& Spares; Consumables / reagents (open, closed system);**	1 x spare set of earpieces, 1 x spare diaphragm.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	NA
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	NA
7. STANDARDS AND SAFETY		
7.1	**Certifications**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	NA

8.3	**Training of staff (medical, paramedical, technicians)**	NA
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	03 Years
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	NA
10.2	**Other accompanying documents**	NA
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	NA

20. Monitor Vital Signs/Multipara Monitor		
Version no. :		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Patient Monitors/Monitoring Systems.
GMDN code(s)		CT1444
GENERAL		
1. USE		
1.1	**Clinical purpose**	Designed to continuously measure and display multiple vital physiological parameters of patients, especially those under critical care.
1.2	**Clinical department/ward**	All Departments
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1. Multichannel (up to 12 leads) ECG measurement and selectable display of upto 5 leads at a time. 2. Temperature probe to be reusable, external skin contact type. Temperature range at least 30 to 40 deg C, minimum gradation 0.1 deg C. 3. Heart rate measurement range to be at least 30 to 250 bpm, with accuracy better than ± 5 bpm and minimum gradation 1 bpm. 4. SpO2 measurement range at least 40-70 % and 70 to 99 %, with accuracy better than ± 1% for 40-70 range and better than ± 3% for 70-99 range and minimum gradation 1%. 5. Blood pressure monitoring range at least 30 to 300 mmHg, minimum gradation 1 mmHg. 6. Respiration rate measurement range at least 0 to 100 bpm, minimum gradation 1 bpm. 7. Trend display of each parameter over at least previous 24 hours to be selectable. 8. LCD screen for displaying all parameters. 9. Audio Visual alarms required: high and low levels for each parameter (operator variable settings), sensor / wire / probe disconnected, low battery.
2.2	**User's interface**	LCD display
2.3	**Software and/or standard of communication**	In-built
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Screen size minimum: 8”X6”.
3.2	**Weight (lbs, kg)**	Light weight
3.3	**Noise (in dBA)**	<50dB.
3.4	**heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through an exhaust cooling fan

3.5	**Mobility, portability**	Portable
	4. ENERGY SOURCE	
4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	Yes
4.3	**Protection**	Electrical protection provided by fuses in both live and neutral supply lines
4.4	**Power consumption**	To be specified by manufacturer
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional) Spare parts (main ones) Consumables/reagents (open, closed system)**	2 pairs, 12 lead ECG cable. 5 sets of ECG connection electrodes (if reusable type). 5 lead ECG cable. Two reusable SpO2 probes for infant use. Two reusable neonatal cuffs. Two external skin temperature probes. Two sets of spare fuses (if non-resettable fuses used). 5 tubes electrode gel (if required).
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Operating condition: – Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.

10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Satisfactory certificate for any existing installation from government hospital
10.2	**Other accompanying Documents**	List of essential spares and accessories, with their part number and cost.
11. NOTES		
11.1	**Other information**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or Warnings**	Any recommendations for best use and supplementary warning for safety should be declared.

21. OXYGEN CYLINDER "D" TYPE		
Version no.:		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Medical gas cylinders
GMDN code(s)		CT 659
GENERAL		
1. USE		
1.1	**Clinical purpose**	A container designed as a refillable cylinder used to hold compressed medical oxygen (O2) under safe conditions at high pressure; O2 is used as an essential life support gas, for anesthesia, and for therapeutic purposes.
1.2	**Clinical department/ward**	All Departments
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1. The high pressure seamless steel cylinder should conform to the standard IS 7285 (Part II) 2004 2. Casing should be made up of high-pressure resistant SS approved by PESO as per Gas Cylinder Rules 2016. 3. The water capacity should be 47L. The hydrostatic test pressure should be 250 bar. 4. Maximum working pressure is 150 bars. 5. Outer casing diameter should be approximately 232 mm. Minimum wall thickness should be 5.2 mm. 6. TARE weight should be approximately 50 Kg. The length of the cylinder should be approximately 1370 mm. 7. The cylinder should have a neck ring, bull nose valve and PESO filling permission. 3. A pressure regulator/flow meter capable of reducing the pressure to an appropriate level to run either a ventilator or provide oxygen therapy. 4. Should be seamless.
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	The capacity should be of 5000 to 6000 Liters at pressure of 1800 - 2000ibs/ square inch.
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**heat dissipation**	NA
3.5	**Mobility, portability**	Trolley for mobility, for Ambulances - to be supplied bare without trolley.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	**Power Requirements**	NA

4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.4	**Power consumption**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional) Spare parts (main ones) Consumables/reagents (open, closed system)**	Humidifier, key and flow meter
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of being operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	NA
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Cylinder should have explosive safety certificate and should be provided along with each cylinder during installation
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Certificate of Calibration, PESO certificate and inspection from the factory.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	10 years warranty
	10. DOCUMENTATION	
10.1	**Manuals**	NA
10.2	**Other accompanying documents**	NA
	11. NOTES	

11.1	**Other information**	NA
11.2	**Recommendations or Warnings**	Color Codes to be displayed on the cylinders.

22. INFUSION PUMP		
Version no. :		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Infusion Pump (Volumetric)
GMDN code(s)		CT 1821
GENERAL		
1. USE		
1.1	**Clinical purpose**	An infusion pump infuses fluids, medication or nutrients into a patient's circulatory system. It is generally used intravenously, although subcutaneous, arterial and epidural infusions are occasionally used.
1.2	**Clinical department/ward**	Emergency, Operation Theatre, Critical Care
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1. Flow rate programmable range at least from 0.1 to 200 ml/hr, in steps of 0.1 ml/hr; and at least from 100 to 1200 ml/hr in steps of 1 ml/hr. 2. Saves last infusion rate even when the AC power is switched off. 3. Bolus rate should be programmable to approx. 500 ml, with infused volume display. 4. Selectable occlusion pressure trigger levels selectable from 300, 500 and 900 mmHg. 5. Accuracy of ±2% or better for set parameters. 6. Maximum pressure generated 20 psi. 7. Pause infusion facility required. 8. Self-check carried out on powering on. 9. Comprehensive alarm package required including: occlusion alarm, near end of infusion pre-alarm and alarm, volume limit pre-alarm and alarm, low battery pre-alarm and alarm, AC power failure, drive disengaged. 10. It should be open system
2.2	**User's interface**	Automatic
2.3	**Software and/or standard of communication**	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Noise free
3.4	**heat dissipation**	NA
3.5	**Mobility, portability**	Yes
4. ENERGY SOURCE		

4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	Internal rechargeable battery having a minimum of 2 hours backup
4.3	**Protection**	Battery powered alarm for power failure or disconnection
4.4	**Power consumption**	As specified by manufacturer
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables/reagents (open, closed system)**	Clamp for mounting pump on IV stand
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of up to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Easy to clean and maintain.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements forsign-off**	Supplier to perform safety and operation check before hand over
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter
	10. DOCUMENTATION	
10.1	**Manuals**	Should provide 2 sets (hardcopy) of: - 1) User, technical, maintenance and service manuals to be supplied along with machine diagrams. 2) List of equipment and procedures required for local calibration and routine maintenance.

		3) Certificate of calibration to be provided by the manufacturer.
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost
11. NOTES		
11.1	**Other information**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or Warnings**	Any warning signs should be adequately displayed

23. OPERATING MICROSCOPE (ENT)		
Version no. :		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Microscopes, light, operating, Otorhinolaryngology
GMDN code(s)		12849
GENERAL		
1. USE		
1.1	**Clinical purpose**	Operating light microscopes designed to magnify minute structures (e.g., nerves, vessels) in the performance of delicate ear, nose, and/or throat (ENT) surgical procedures, which require high magnification and adjustable focusing ENT operating microscopes typically consist of a stereo microscope (standard or modified) and a mobile floor stand or wall or ceiling mount.
1.2	**Clinical department/ward**	ENT department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1. Should be mobile floor stand on four caster wheels for easy handling and absolute stability with brake. 2. Should have apochromatic optics and should have LED Light Source with bright natural Light. 3. Should have Manual Fine Focusing 4. Should have Focal Distance of Objective Lens (F 200 mm) 5. Should have three step magnification: 5x, 10x & 20x and should have total magnification from at least 0.6x to 1.6x 6. Additional objective lenses of 250mm and 300 mm and 400mm should be supplied. 7. Eye pieces should be minimum 10x or 12.5x or 15x paired super wide field with eye guards. 8. Should have universal coupling. 9. Should have 90-degree binocular with converging optics 10. Should have cold light coaxial illumination by fiber light guide 11. Should have tools free design for stand-by bulb change over and for failed bulb replacement 12. Should have heat absorbing and UV filters. 13. Should have in-built green and cobalt blue filters. 14. Should have counter balanced arm mechanism. 15. Should have a minimum vertical stroke of 400mm
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication**	NA

3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	<50dB
3.4	**heat dissipation**	Heat dissipation should maintain nominal temperature and the heat should be disbursed through an exhaust cooling fan.
3.5	**Mobility, portability**	Mobile floor, stand or wall or ceiling mount.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	Battery operated light source.
4.3	**Protection**	Voltage corrector/stabilizer to allow operation at ± 30% of local rated voltage.
4.4	**Power consumption**	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional) Spare parts (main ones) Consumables/reagents (open, closed system)**	1. Beam splitter with 'C' Mount. 2. Motorized with foot control 3. Objective lens 250 mm, 300 mm, 400 mm. 4. Monocular assitoscope. 5. Binocular assitoscope 6. Battery operated light source.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	**Requirements forsign-off**	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.

8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. DOCUMENTATION		
10.1	**Manuals**	Should provide 2 sets (hardcopy) of: - 1. User, technical, maintenance and service manuals to be supplied along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Certificate of inspection and calibration. 4. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying Documents**	List of important spares and accessories, with their part numbers and cost
11. NOTES		
11.1	**Other information**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or Warnings**	Any warning signs should be adequately displayed

24. OXYGEN CONCENTRATORS		
Version no. :		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Oxygenators
GMDN code(s)		CT1608
GENERAL		
1. USE		
1.1	**Clinical purpose**	To concentrate oxygen (O2) from ambient air and deliver the concentrated O2, typically through an attached nasal cannula, to a patient requiring oxygen therapy
1.2	**Clinical department/ward**	OT, ICU, SNCU/NICU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1. Flow rate: 0~5 LPM, purity > 93%. 2. O2 delivery pressure: 0.03 to 0.07 Mpa (4.35 - 10.15 PSI). 3. Atomizing pellet (ml/min.) > 0.5, uninterrupted flow of oxygen. 4. Oxygen monitoring system (optional). 5. Low pressure alarm, high pressure alarm and power failure alarm. 6. Unit capable for supplying oxygen to two outlets simultaneously using two independent flow meters.
2.2	**User's interface**	Front panel access to reset switch.
2.3	**Software and/or standard of communication**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	Max 30 kg
3.3	**Noise (in dBA)**	<50dB
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Mobile
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.4	**Power consumption**	As specified by manufacturer.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)**	Humidifier Bottles-4nos, power cord-1no. Nasal Cannula with extension tubing-2 nos; Gross particle cabinet filter, compressor intake filter and bacterial filter of

	Consumables/reagents (open, closed system)	0.8-1.0 micron; geolite crystal
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90 %.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements forsign-off**	Supplier to perform safety and operation check before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance should be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
	10. DOCUMENTATION	
10.1	**Operating manuals, set manuals, other manuals**	User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams.
10.2	**Other accompanying documents**	NA
	11. NOTES	
11.1	**Other information**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or Warnings**	Any recommendations for best use and supplementary warning for safety should be declared.

25. OT LIGHT - SHADOWLESS LAMP CEILING TYPE MAJOR		
Version no.:		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Shadowless lamp ceiling type major
GMDN code(s)		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	Luminescence shadow less lamp adopts light sources different positions for focus to eliminate shadows of different parts of medical workers.
1.2	**Clinical department/ward**	Operation Theater
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1) Double dome 2) Intensity Control in 9 steps for individual domes 3) Height Adjustment :600mm 4) Action Radius :1850mm 5) Possible Movements: Radial, Angular & Axial 6) Colour Temperature :4500K and above 7) LED technology: minimum 40,000 hours lamp life 8) Intensity, brightness, contrast and power switch to be made available on handle/wall-check. 9) Focal distance(d1+d2) =0.8 to 1.2 m 10) Temperature rises on the keep of surgeries to be less than 10° 11) CR± approx. 95 or more 12) 360° rotation for both arms
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through an cooling mechanism
3.5	**Mobility, portability**	Stationary
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz

4.2	**Battery operated**	Yes
4.3	**Protection**	Should have over-charging cut-off with visual symbol.
4.4	**Power consumption**	As specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables/reagents (open, closed system)**	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Easy to clean and maintain.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	**Requirements forsign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance should be provided
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years
10. DOCUMENTATION		
10.1	**Manuals**	Should provide 2 sets (hardcopy and soft-copy) of:- 1) User, technical and maintenance manuals to be supplied in English/ Hindi language along with machine diagrams.
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost
11. NOTES		

11.1	**Other information**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or Warnings**	Any warning signs should be adequately displayed

26. OT LIGHT-SHADOWLESS LAMP CEILING TYPE MINOR		
Version no. :		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Shadowless lamp ceiling type minor
GMDN code(s)		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	Luminescence shadow less lamp adopts light sources different positions for focus to eliminate shadows of different parts of medical workers.
1.2	**Clinical department/ward**	Operation Theatre
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1) Single dome 2) minor dome 3) Intensity Control: continuous (1,00,000 Lux) 4) Height Adjustment :600mm 5) Action Radius :1850mm 6) Possible Movements: Radial, Angular & Axial 7) Colour Temperature :4500 and above 8) LED technology: minimum 40,000 hours lamp life 9) Intensity, brightness, contrast and power switch to be made available on handle/wall-check. 10) Focal distance(d1+d2) =0.8 to 1.2 m 11) Temperature rises on the keep of surgeries to be less than 10° 12) CR± approx. 95 or more 13) 360° rotation for both arms
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through an cooling mechanism
3.5	**Mobility, portability**	Ceiling Type
4. ENERGY SOURCE		

4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	Yes
4.3	**Protection**	Should have over-charging cut-off with visual symbol.
4.4	**Power consumption**	As specified by manufacturer.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables/reagents (open, closed system)**	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Easy to clean and maintain.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	**Requirements forsign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users on operation and basic maintenance.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	03 years
10. DOCUMENTATION		
10.1	**Manuals**	Should provide 2 sets (hardcopy and soft-copy) of:- User, technical and maintenance manuals to be supplied in English/ Hindi language along with machine diagrams.

10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost.
11. NOTES		
11.1	**Other information**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or Warnings**	Any warning signs should be adequately displayed

27. OT LIGHT -SHADOWLESS LAMP CEILING MOBILE/OPERATING LAMP		
Version no. :		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Shadowless lamp standing model
GMDN code(s)		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	Luminescence shadow less lamp adopts light sources different positions for focus to eliminate shadows of different parts of medical workers.
1.2	**Clinical department/ward**	Operation Theatre
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1) Dome Head :515mm Dia 2) LED lights-2 nos 3) Lockable castors stand with minor dome 3) Light intensity at 1 mt. :1,00,000 Lux 4) Intensity Control: Continuous 5) Height Adjustment :600 mm approx. 6) Action Radius :1250mm 7) Possible Movements: Radial, Angular & Axial 8) Colour Temperature :4500K or above 9) Temperature Rise in field :3°-6° c from ambient temperature 10) Control Panel at the dome 11) CR± 95000 12) Lamp life:40,000 hours 13) Battery back-up:1 hour 14) Auto-power off and over-charging cut-off.
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism
3.5	**Mobility, portability**	Mobile
4. ENERGY SOURCE		

4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	Yes
4.3	**Protection**	Should have over-charging cut-off with visual symbol.
4.4	**Power consumption**	As specified by manufacturer
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables/reagents (open, closed system)**	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Easy to clean and maintain.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	**Requirements forsign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users on operation and basic maintenance.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	03 years warranty
	10. DOCUMENTATION	
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hardcopy and soft-copy) of: - User, technical and maintenance manuals to be supplied in English/ Hindi language along with machine diagrams.

10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost
11. NOTES		
11.1	**Other information**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or Warnings**	Any warning signs should be adequately displayed

28. Wheel Chair		
Version no.:		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Wheel Chairs
GMDN code(s)		14449
GENERAL		
1. USE		
1.1	**Clinical purpose**	Chairs mounted on large wheels, designed for indoor (e.g., hospital, institution, home) or outdoor transportation of patients or individuals with impaired walking ability.
1.2	**Clinical department/ward**	All Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1. Overall size 670 mm W x 1120mm D x 920 mm H. 2 Should be made of 16 gauge SS 304 grade tube frames and 16 gauge SS 304 sheet for seat & back rest. 3. Should have a fixed arm rest. 4. Should have Reticulated and breathable cushion 5 Should have minimum 6 swivel nylon caster front wheel, 24" bicycle type rear wheel with pneumatic tyre. 6. Two handles are provided with the hand grips 7. Back wheel fixing bolt shall be covered with cup type nut. 8. Should have breaking system on both side 9. All pipes & Foot rest should be made of aluminum
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Mobile
4. ENERGY SOURCE		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.4	**Power consumption**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		

5.1	**Accessories (mandatory, standard, optional) Spare parts (main ones) Consumables/reagents (open, closed system)**	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	**NA**
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Easy to clean
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	Should conform to ISO 13485 quality standards.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	NA
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	03 Years
	10. DOCUMENTATION	
10.1	**Manuals**	NA
10.2	**Other accompanying Documents**	NA
	11. NOTES	
11.1	**Other information**	NA
11.2	**Recommendations or Warnings**	NA

29. CRYOSURGICAL UNITS, OPHTHALMIC (CO_2 and N_2O)		
Version no.:		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Cryosurgical Units, Ophthalmic
GMDN code(s)		11068
GENERAL		
1. USE		
1.1	**Clinical purpose**	Cryosurgical units are designed for applying extreme cold to eye tissues to destroy abnormal cells. These units usually consist of a hollow probe (cryo probe) that circulates a cryogenic substance (e.g., liquid nitrogen) to form an ice crystal ball around the cells, which freezes the cells of the tissues with which it comes into contact. Ophthalmic cryosurgical units are used mainly to treat eye tumors (e.g., retinoblastoma), to relieve ingrown eyelashes (trachiasis), for cryo extraction of intra capsular cataracts, and/or to repair retinal detachmen
1.2	**Clinical department/ward**	Ophthalmology - Operating theater, Operating room
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1. Cryogen shall be CO2 and N2 O. 2. Cryosurgical unit capable of achieving temperatures at the cryo tip below -79°C (-110.2°F) for CO2, -89°C (-128.2°F) for N2O. 3. Should have active and passive defrosting system. 4. Cryosurgical procedures require several different probe designs. Special probes are used based on surgical procedures. Cryosurgical units with multiple probe tips can enable physicians to perform a number of specialized procedures. Should be supplied with all kinds of probes required for ophthalmology and all cryo probes must be autoclavable. 5. Operating pressure 400 to 850 psi. 6. The unit shall have a trigger mechanism to control the freeze/thaw cycle (active defrost preferred but not essential), removable circular, closed design cryo tips with flat surfaces or with a cone extrusion not exceeding 5 mm, insulated cryo shaft of length 170 mm to 200 mm, hose assembly (high pressure) with cylinder connector, pressure gauge and relief valve, and exhaust port to which a hose can be connected to safely vent the exhaust gas. 7. Due to the adverse effects of chronic exposure to waste anesthetic gases, nitrous oxide units should have scavenging ability.
2.2	**User's interface**	Manual

2.3	**Software and/or standard of communication**	NA
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)	
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.4	**Power consumption**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables/reagents (open, closed system)**	1. Cryo probes according to the specific use (Preferably 3 sizes (1.5 mm, 2 mm, 3 mm)). 2. Integral timer and temperature indicator. 3. Should be supplied with rolling cart. 4. Should be supplied with unfilled cylinder for N2O or CO2 .
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements forsign-off**	Supplier to perform safety and operation checks before handover.

8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. DOCUMENTATION		
10.1	**Manuals**	Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams.
10.2	**Other accompanying Documents**	List of important spares and accessories, with their part numbers and cost
11. NOTES		
11.1	**Other information**	Contact details of manufacturer, supplier, and local service agent to be provided.
11.2	**Recommendations or Warnings**	Any warning sign would be adequately displayed.

30. CRYOSURGICAL UNITS, OPHTHALMIC (LIQUID NITROGEN)		
Version no. :		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Cryosurgical Units, Ophthalmic
GMDN code(s)		11068
GENERAL		
1. USE		
1.1	**Clinical purpose**	Cryosurgical units designed for applying extreme cold to eye tissues to destroy abnormal cells. These units usually consist of a hollow probe (cryo probe) that circulates a cryogenic substance (e.g. liquid nitrogen) to form an ice crystal ball around the cells, which freezes the cells of the tissues with which it comes into contact. Ophthalmic cryosurgical units are used mainly to treat eye tumors (e.g., retinoblastoma), to relieve ingrown eyelashes (trachiasis), for cryo extraction of intra capsular cataracts, and/or to repair retinal detachment.
1.2	**Clinical department/ward**	Ophthalmology - Operating theater, Operating room
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1. Cryogen shall be Liquid Nitrogen. 2. Cryosurgical unit capable of achieving temperatures at the cryo tip below --196°C (-320.8°F). 3. Should have Active and Passive defrosting system. 4. Cryosurgical procedures require several different probe designs. Special probes are used based on the surgical procedures. Cryosurgical units with multiple probe tips can enable physicians to perform a number of specialized procedures. Should be supplied with all kinds of probes required for ophthalmology and all cryo probes must be autoclavable. 5. Operating pressure 400 to 850 psi. 6. The unit shall have a trigger mechanism to control the freeze/thaw cycle (active defrost preferred but not essential), removable circular, closed design cryo tips with flat surfaces or with a cone extrusion not exceeding 5 mm, insulated cryo shaft of length 170 mm to 200 mm, hose assembly (high pressure) with cylinder connector, pressure gauge and relief valve, and exhaust port to which a hose can be connected to safely vent the exhaust gas.
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication**	NA
3. PHYSICAL CHARACTERISTICS		

3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**heat dissipation**	NA
3.5	**Mobility, portability**	Portable
	4. ENERGY SOURCE	
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.4	**Power consumption**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional) Spare parts (main ones) Consumables/reagents (open, closed system)**	1. Cryo probes according to the specific use (Preferably 3 sizes (1.5 mm, 2 mm, 3 mm)). 2. Integral timer and temperature indicator. 3. Should be supplied with rolling cart. 4. Should be supplied with unfilled cylinder for N_2O or CO_2.
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity upto 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements forsign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users on operation and basic maintenance.
	9. WARRANTY AND MAINTENANCE	

9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. DOCUMENTATION		
10.1	**Manuals**	Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams.
10.2	**Other accompanying Documents**	List of important spares and accessories, with their part numbers and cost
11. NOTES		
11.1	**Other information**	Contact details of manufacturer, supplier, and local service agent to be provided.
11.2	**Recommendations or Warnings**	Any warning sign should be adequately displayed.

31. INTERFERENTIAL THERAPY UNIT		
Version no. :		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Interferential Therapy Unit
GMDN code(s)		11248
GENERAL		
1. USE		
1.1	**Clinical purpose**	Therapeutic ultrasound units convert electrical energy to high- frequency (i.e., 1 or 3 megahertz [MHz]) sound waves that penetrate tissues to produce pain relief and facilitate tissue healing through thermal and non-thermal physiologic reactions
1.2	**Clinical department/ward**	Physical Therapy Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1. Dual output Channels and isolated between channels 2. Should have 0-30 operation programs 3. Symmetrical Balanced Sine Wave 4. Output Current:0-100 mA 5. Interference Frequency 2-160 Hz 6. Output Frequency 4000Hz (with ±1% tolerance) fixed on Channel 1 7. Modulating Frequency 4002 4160Hz (with ±1% tolerance) adjustable on Channel 21 8. Treatment Timer Continuous, 15, 30, 45 or 60 minutes 9. 2pole/4pole multi vector mode 10. Patient safety fuse/Auto cut-out
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication**	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Noise pressure level (< or = 60)dBA
3.4	**heat dissipation**	Should maintain a nominal temp and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz

4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by the manufacturer
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables/reagents (open, closed system)**	1. one set patient wire IFT 2. Two set fixation straps 3. One gel bottle 4. One power cable 5. One operating manual 6. Big and small rubber electrode
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements forsign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users on operation and basic maintenance.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
	10. DOCUMENTATION	
10.1	**Manuals**	Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine

		diagrams.
10.2	**Other accompanying Documents**	List of important spares and accessories, with their part numbers and cost
11. NOTES		
11.1	**Other information**	Contact details of manufacturer, supplier, and local service agent to be provided.
11.2	**Recommendations or Warnings**	Any warning sign should be adequately displayed.

32. EXERCISE COUCH/TABLE		
Version no.:		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Exercise Plinth/Couch
GMDN code(s)		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	Tables are designed for the treatment of diseases using therapeutic exercises and massage. It may be used for all purpose related to PMR department.
1.2	**Clinical department/ward**	Physical Therapy Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1. Made up of solid wood. Should have 4 legs 2. Plinth size: high and low 3. Top 19mm thickness ply. 4. 4 inch cushioned with rexin cover legs cross section 8 x 10cm. L*B*H*(to be specified as per the requirements)
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	NA
4. ENERGY SOURCE		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.4	**Power consumption**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables/reagents (open, closed system)**	Exercise plinth High and exercise plinth Low

6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	**NA**
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	NA
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	Should conform to ISO 13485 quality standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements forsign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	NA
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	NA
10. DOCUMENTATION		
10.1	**Manuals**	NA
10.2	**Other accompanying Documents**	NA
11. NOTES		
11.1	**Other information**	NA
11.2	**Recommendations or Warnings**	NA

33. WEIGHING SCALE		
Version no.:		02
Date:		August 2023
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	Clinical purpose	Weighing scale is used to measure body mass.
1.2	Used by clinical department/ ward	OPD
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Should be made of sturdy mechanical structure to support/withstand heavy workload in public health centre. 2. Platform size 350 x 350 mm (Tolerance +/- 10%) 3. Measuring capacity should be at least 150 kg with accuracy up to 100 gms. 4. The display should be LCD/LED with four digits. The size of display should be minimum height 24 mm for clear visibility. 5. The scale should operate on electricity as well as on inbuilt re-chargeable batteries. 6. The reading should get locked automatically at stable weight and their should be an indication for the same. 7. The scale should have readings in SI system (Kgs and Gms). 8. The scale should have auto off feature when not in use. 9. It should be able to record weight in less than 05 seconds. 10. Built in rechargeable battery.
2.2	User's interface	LCD/ LED display.
2.3	Software and/or standard of communication (wherever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	NA

3.3	Configuration	N.A.
3.4	Noise (in dBA)	N.A.
3.5	Heat dissipation	NA
3.6	Mobility, portability	Portable
	4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO2)	
4.1	Power Requirements	220 V AC +/- 10%, 50 Hz
4.2	Battery operated	Rechargeable battery
4.3	Protection	NA
4.4	Power consumption	NA
4.5	Other energy supplies	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	Accessories (mandatory, standard, optional), Spare parts (main ones), Consumables / reagents (open, closed system)	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	Easy to clean
	7. STANDARDS AND SAFETY	
7.1	Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
	8. TRAINING AND INSTALLATION	
8.1	Pre-installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	NA
	9. WARRANTY AND MAINTENANCE	
9.1	Warranty	• 03 years • Preventive Maintenance visits at least once in each quarter

10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	NA
10.2	Other accompanying documents	NA
11. NOTES		
11.1	Service Support Contact details (Hierchy Wise; including a toll free/landline number)	Contact details of the manufacturer should be provided.
11.2	Recommendations or warnings	Any warning sign should be displayed adequately.

34. Baby Weighing Scale		
Version no.:		02
Date:		August 2023
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Infant Scale, Electronic
GMDN code(s)		35324
GENERAL		
1. Use		
1.1	**Clinical purpose**	It is used to measure the weight of an infant, particularly a newborn, or to monitor weight changes.
1.2	**Used by clinical department/ ward**	Midwifery Led Care Unit/NICU/SNCU/PICU
TECHNICAL		
2. Technical characteristics		
2.1	**Technical characteristics (specific to this type of device)**	• Tabletop, light, portable and digital precision weighing scale. • Should have easy to read backlit digital display. • Weight displays up to 2 decimal point in Kg/gm. • Weighing pan should be skin friendly, non-toxic durable material suitable for weighing newborn babies and the construction should not allow the baby to slip from the tray. • The Tray should be made of ABS/ Acrylic and must be devoid of any sharp edges. • Easy to clean baby tray. • Zero weight adjustment facility. • Quick, clear digital read outs. • Measurement does not change with position of baby on the pan. • Provision to measure the height of the baby in its laying position. • Accuracy: +/- 5 mg, Measuring limit: 10 gm to 20 kg. • Built in rechargeable battery/ AC mains.

2.3	**User's interface**	Backlit Digital Display
2.4	**Software and/or standard of communication(wherever required)**	NA
	3. Physical Characteristics	
3.1	**Dimensions (metric)**	Pan size : 500-550 mm x 300-350 mm x 80-100 mm
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dba)**	N.A.
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
	4. Energy source	
4.1	**Power requirements**	220 V AC +/- 10%, 50 Hz
4.2	**Battery operated**	Built in rechargeable battery /AC mains
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by the manufacturer
	5. Accessories, spare parts, consumables	
5.1	**Accessories (mandatory, standard, optional);Spare parts (main ones); Consumables / reagents (open, closed system)**	NA
	6. Environmental and departmental considerations	
6.1	**Atmosphere / ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90%.
6.2	**User's care, cleaning, Disinfection & sterility issues**	Easy to clean.
	7. Standards and Safety	
7.1	**Certificates (pre-market, sanitary, ..);**	1. Should be CDSCO approved. 2. Should comply with BIS standards.

	performance and safety standards (specific to the device type); local and/or international	3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. Training and Installation		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	NA
9. Warranty and Maintenance		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. Documentation		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams.
10.2	**Other accompanying documents**	NA
11. Notes		
11.1	**Service support contact details (hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

35. ICU BED-MOTARISED WITH RESUSCITATION MODE (RESUSCITATION BED)		
Version no.:		01
Date:		August 2023
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		Basic electric hospital bed
GMDN Code		34870
GENERAL		
1. USE		
1.1	Clinical Purposes	ICU beds are special hospital beds designed for ICUs to take care of critical patients and can be operated electro-mechanically. ICU beds facilitates comfortable transfer to and fro and has a provision of bedside diagnostic including X-ray investigations. Thus, they provide safety, comfort and convenience to the patients and caregivers alike.
1.2	Used by clinical department/ward	ICU (Intensive Care Unit)
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical Characteristics	I. Should have fully motorised 4 sections and sectional mattress. II. Should have 4 separate electrically operating function through embedded control panel/handheld wired remote control for Height adjustment (Hi-Low), Back rest, Knee rest and Trendelenburg/Reverse Trendelenburg. III. The bed frame should be made of Stainless-steel SS (304)with epoxy coating. IV. Should have ABS/polymer moulded head and foot board panels detachable. V. Should have ABS/polymer moulded swing down safety side railing on both sides. VI. Should have a provision for carrying out whole body X-ray at the bedside. VII. Should have digital/analog indicators for angle display.

		VIII. Should have one touch key provision on control panel for CPR position and manual CPR option in case of automatic system failure. IX. Bed position adjustments should have: Back Rest angular movement in range from 0-70 deg or more; Knee rest angular movement in range from 0-45 deg or more; Trendelenburg and Reverse Trendelenburg: 0-12 deg or more; X. Should have a therapeutic Weight bearing up to 150-200 Kg XI. Should have heavy duty casters made up of Stainless Steel (304) ball bearing/ABS/Polyester with dual locking arrangement. XII. Should have provision for holding IV pole on four corners. XII. High density foam mattress washable and detachable in 4 parts XIII. Should have battery backup of at least 1 hour XIV. Clearance between Bed Base frame and Floor surface in adjustable range from mm: 120-150 mm
2.2	User's Interface	Electro-mechanical (motorised)
2.3	Software and/ or standard of communication (wherever required)	NA
3. PHYSICAL CHARACTERISTIC		
3.1	Dimensions (in cm)	1. Length: 2100-2300 mm 2. Width: 900-1100 mm
3.2	Weight	To be specified by the Manufacturer/Supplier;
3.3	Noise	Less than 50dB;
3.4	Heat Dissipation	Not applicable
3.5	Mobility/Portability	Should be easily movable with minimal physical effort.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2.....)		
4.1	Power inputs	220 +/- 10% VAC, 50 Hz
4.2	Power consumption	To be specified by Manufacturer/Supplier;
4.3	Battery backup	Battery backup with inbuilt charger shall be provided.
5. ACCESSORIES. SPARE PARTS AND CONSUMABLE		

5.1	Accessories, (mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system)	I. Should be provided with IV rods; II. Mattress as per the specs specified in Section (2.1) III. Side rails IV. X-ray cassette tray, Urine bottle holder and drainage bottle holder
BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere /Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Easy to clean and disinfect.
7. STANDARDS & SAFETY		
7.1	Certificates (pre-market, sanitary); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	Requirements for sign-off	Supplier to perform safety and operation check before hand over.
8.3	Training of staff (medical, paramedical, technicians)	Training of User on operation and basic maintenance.
9. WARRANTY AND MAINTENANCE		

9.1	Warranty	3 years including all spare parts and accessories.

10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Satisfactory certificate for any existing installation from government hospital
10.2	Other accompanying documents	List of essential spares and accessories with their part number and cost.
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any warning sign should be adequately displayed.

36. Mobile Spotlight		
Version no. :		02
Date:		August 2023
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		Mobile Examination/Treatment Room Light
GMDN code(s)		36843
GENERAL		
1. USE		
1.1	Clinical purpose	A mobile device intended to provide light to illuminate a site of patient examination and/or treatment.
1.2	Used by clinical department/ward	Examination Room, Minor OT
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Should use a LED light source. 2. It should have variable light intensity upto 50000 Lux. 3. Knob or buttons for adjusting the light intensity between 20,000 to 50,000 Lux. 4. Lifespan of LED lamp should not be less than 30000 hours. 5. It should have wide field size of illumination. 6. Arm should be adjustable horizontally, vertically and easy to focus on all directions. 7. It should have an on/off switch. 8. The stand should be heavy, and it should have 360 deg roller wheels (Angular/SS MS-304) with locking mechanism.
2.2	User's interface	Manual
2.3	Software and/or standard of communication (wherever required)	Not required
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	Height should be adjustable.
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA

3.5	Mobility, portability	Mobile
4. ENERGY SOURCE		
4.1	Power requirements	220 +/- 10% VAC, 50 Hz
4.2	Battery operated	Yes, Minimum backup time of 02 hour
4.3	Protection	NA
4.4	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Not required.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	Easy to clean
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Compatible electrical accessories as per standard Indian set-up.
8.2	Requirements for sign-off	Supplier to perform safety and operation check before handover.
8.3	Training of staff (medical, paramedical, technicians)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	03 Years
10. DOCUMENTATION		

10.1	Operating manuals, set manuals, other manuals	One copy (hard copy and soft copy) to be provided on user manual/ operating manual and service/Technical manual.
10.2	Other accompanying documents	List of essential accessories and cost should be quoted.
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed on equipment.

37. OTOSCOPE		
Version no. :		02
Date:		August 2023
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		Otoscope
GMDN code(s)		12849
GENERAL		
1. USE		
1.1	Clinical purpose	An otoscope is a tool which is used to examine structures of the ear, particularly the external auditory canal, tympanic membrane and middle ear.
1.2	Used by clinical department/ward	ENT department.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. At least 2.5 V Xenon or halogen light source. 2. Should be convenient pocket type otoscope. 3. Swivelling viewing with at least 3X magnification. 4. Should be able to detach the otoscope head. 5. Should provide no reflections and obstructions. 6. Should provide detachable accessories of various sizes. 7. Should have in built rechargeable battery. Recharge should be possible with direct mains supply.
2.2	User's interface	Manual
2.3	Software and/or standard of communication (wherever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Portable
4. ENERGY SOURCE		

4.1	Power requirements	Rechargeable battery
4.2	Battery operated	Should have built in rechargeable battery. Recharge should be possible with direct mains supply.
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Set of plastic specula, varying diameters between 2.0 and 5.0 mm Two spare bulbs At least 10 reusable (autoclavable) otoscope specula for each of the following measure: 2, 3 and 5 mm.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	Supplier to perform safety and operation check before handover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	03 Years
10. DOCUMENTATION		

10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams.
10.2	Other accompanying documents	NA
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any warning sign should be adequately displayed on equipment.

38. Foetal doppler / Fetoscope		
Version		02
Date:		August 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Foetal Doppler System
GMDN code(s)		34040
GENERAL		
1. USE		
1.1	Clinical purpose	It is used non-invasively to detect fetal heart beats using ultrasound/doppler technology. The fetal heart beats are typically conveyed audibly via the measuring/display unit and attached probe which is applied to the surface of the pregnant women's abdomen.
1.2	Used by clinical department/ward	Midwifery Led Care Unit/Obstetric/ANC clinic.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. It should measure fetal heart rate (FHR) accurately. 2. It should have a back light display. 3. The probe should be highly sensible to pick up FHR. 4. The probe should be waterproof. 5. Probe (transducer) with 2-5 MHz frequency attached via a cable. 6. It should give an indication of low battery. 7. It should have built-in-speaker with volume adjustment. 8. Built-in rechargeable Li-on battery with minimum back up of 6-8 hours.
2.2	User's interface	Backlit Digital Display
2.3	Software and/or standard of communication (wherever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA

3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA),	Noise: <60dBA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Yes, Handheld device
	4. ENERGY SOURCE	
4.1	Power Requirements	220 V +/- 10% AC, 50 Hz
4.2	Battery operated	Built-in rechargeable battery with minimum backup of 6-8 hour
4.3	Power consumption	To be specified by manufacturer
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)	Doppler probe, battery charger, gel for application of probe.
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity upto 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer
	7. STANDARDS AND SAFETY	
7.1	Certificates (pre-market, sanitary, ..)	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
	8. TRAINING AND INSTALLATION	

8.1	Pre-installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	Supplier to perform safety and operation check before handover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	Warranty	• 03 years • Preventive Maintenance visits at least once in each quarter.
	10. DOCUMENTATION	
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hardcopy and soft copy) of: 1. User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and copy) to be provided. 3. Satisfactory certificate for any existing installation from government hospital
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost.
	11. NOTES	
11.1	Service Support Contact details (Hierarchy wise; including a toll free/landline number)	Contact details of manufacture, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any warning sign should be adequately displayed.

39. Color Doppler Ultrasound/Obs/Gynae Ultrasound		
Version		02
Date:		August 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	**Clinical purpose**	Doppler ultrasound uses sound waves to detect the movement of blood in vessels. It is used in pregnancy to study blood circulation in the baby, uterus and placenta.
1.2	**Used by clinical department/ward**	Radiology laboratories
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	The system should be with full Digital Technology & should be capable of whole-body sonography & other application for adult & paediatrics (Infants & Neonates) which includes abdominal, Obs/Gyn, Endovascular, Peripheral vascular, transcranial, transvaginal, transrectal & small parts. 1) The system should incorporate facility for high resolution 2D, 3D, M mode, PW color imaging, Power Doppler Angio Imaging Modes. 2) The system should have more than 20000 Digital Channels & on the site to higher number of channels (preferable). 3) The system should have 256 Grey shade or more. 4) The system should have capability of triplex display in real time with all probes. 5) The system should have a very high frame rate of 700 frames per second or more. 6) The system should have Harmonic imaging for hard to image patients. The system shall support Tissue Harmonic Imaging capability on phased, linear, 3D and curved array transducers.

		7) The system should have advance image processing algorithms to analyze between targets & artifacts so as to sharpen target anatomy, reduce the sparkle & artifacts to improve image quality. 8) The system shall offer Harmonic Imaging in Power Doppler Imaging mode for improved sensitivity and specificity in differentiating blood/ agent from tissue. 9) The system should have facility for Zoom(Real-time and Frozen-image) & manipulation of image through pre-processing and post-processing with cine loop viewing image of all modes. 10) System should have disc of atleast 500 GB or more. 11) The system should have facility of digital storage & retrieval of B/W & color image data(Both frozen & cine loops) on built in as well as ramble media(CD, DVD)USB port. 12) The system should have automatic real time quantification of Doppler parameter like velocity, frequency, time heart rate stop, flow volume, plasticity index, resistivity index, peak velocity, average value, point value, area & diameter flow volume etc. 13) The system should have high dynamic range of 170 dB with scanning depth of 30 cm or more. 14)All transducers(minimum 3) should be broad bandwidth, Frequency range 2 to 12 MHz or more with universal ports for transducer interchange. Two active ports and one parking probe is required. 15) System should have 19" HD display with tilt and swivel Facility along with alphanumeric keyboard with illuminating keys and status function. 16) Dicom 3.0 compatible. 17)Review of stored images is desirable
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication(wherever required)**	In-built
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA),**	Noise Free system

3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Room Installation
	4. ENERGY SOURCE	
4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	No
4.3	**Protection**	Should have over-charging cut-off with visual symbol.
4.4	**Power Consumption**	To be specified by manufacturer
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional);** **Spare parts (main ones);** **Consumables / reagents (open, closed system)**	Machine should be supplied with following transducers: I. Broad band convex array transducer with multi-frequency range of 2 to 5 MHz or wider range-1 No. II. Broad band transvaginal/transrectal probe with multi-frequency range between 5 to 8 MHz or wider range-1 No. III. Linear probe Transducer 5 to 12 MHz or more. The system should have following devices: a) Laser color printer for color image printing b) B/W Thermal printer of latest model c) Glazed thermal paper rolls 50 no. & 5 rim of Glossy paper sheet. d) Online Ups for power back up of minimum 30 minutes e) 50 nos. of CDs to be supplied
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type);**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.

	Local and/or international	5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users on operation and basic maintenance should be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. Documentation		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Advanced maintenance tasks documentation. 4. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

40. DENTAL CHAIR WITH ACCESSORIES		
Version no.:		02
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		Chairs, Examination/Treatment, Dentistry
GMDN code(s)		10792
GENERAL		
1. USE		
1.1	**Clinical purpose**	Examination/treatment chairs designed to facilitate dental examination, treatment, and/or minor surgical procedures. These chairs are typically adjustable up to a height that allows the healthcare staff to perform procedures while standing; the chairs usually include head and armrests, a reclining back that may be tilted from a vertical to a horizontal or near-horizontal position, and rotating capabilities to facilitate examination and/or treatment.
1.2	**Used by clinical department/ward**	Dental Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. It should have double articulating headrest with seesaw movement. 2. It should be provided with soft cervical support. 3. Dental unit should have latest overhead delivery system. 4. It should have two 3-way syringes (Tip autoclavable, with spare tips) one on unit side and other on the assistant side. 5. It should have two high speed Air rotor terminals with two rotor hand pieces and accessories and one terminal for fiber optic. One for air motor/micro motor having straight and contra angle hand pieces and other for air rotor terminal with two air rotor hand pieces with two spare cartridges. 6. It should have LED light cure unit with minimum intensity 1200 mW/cm^2. 7. It should have infection control system with non-retraction valves (Bio system/equivalent). 8. All hand pieces/terminals should be kept on Autoclavable pads. 8 spare autoclavable pads should be supplied. 9. Arm of unit should be pneumatically locked.

		10. All air tubing of the delivery system can be disinfected internally after every dental procedure. 11. It should have one in built piezo ultrasonic scalar (max frequency should be 36 kHz) 12. Removable auxiliary tray (autoclavable) shall be supplied – 10 sets. 13. It should have integrated latest foot operated LED light (30000 - 50000 Lux). 14. It should have rotatable water system with removable spittoon. 15. It should have Medium Vacuum Suction and high suction (Motorized Suction). 16. Should have following multiple program • Two programmable working positions. • Splitting and last working position with light ON and OFF automatically. • Return to Zero position with light OFF automatically. • It should have emergency stop control with luminous indication. • Programmable bowl water and cup filler water. 17. It should have LED based X-ray viewer (For I.P.G/O.P.G films). 18. It should be provided with right arm. 19. It should have multi-functional foot control base. 20. It should be provided with two stools with adjustable backrest tilt including an adjustable ring for foot rest 21. Oil free medical grade compressor of 1HP (fully imported)
2.2	**User's interface**	Manual
2.3	**Software and/ or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Noise-free system
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism
3.5	**Mobility, portability**	Stationary Installation
4. ENERGY SOURCE		
4.1	**Power requirements**	220 +/- 10% VAC, 50 Hz

4.2	**Battery operated**	No
4.3	**Protection**	Stabilizer or inbuilt protection to voltage fluctuation/current surge.
4.4	**Power consumption**	To be specified by manufacturer.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	**LED LIGHT CARE UNIT:** 1. Ensures up to 1200 mW/ sq.cm **ULTRASONIC SCALAR:** 1. Piezotronics Scalar with frequency of 28000-36000 Hz 2. Autoclavable hand piece, Total control is Microprocessor based 3. Hand Pieces most sleek. 4. The scalar supplies with: Piezotronics scalar with 4 tips. **FOOT OPERATED LIGHT:** 1. LED light with 3 intensity with 3 axis movement. 2. Intensity is between 30000 - 50000 Lux 3. On/off Switch by sensor switch - non touch. 4. Step intensity control by non-touch sensor. **AIR ROTOR:** 1. Air Rotor hand piece clean head with a speed of 350000 RPM 2. Supplies with a. Titanium/ SS Air rotor torque hand piece. b. Ultra push type non retraction valve. **BRUSHLESS MICROMOTOR:** 1. It should have digital display of speed. 2. High Torque Micro motor (Foot Controlled) with Speed range of 2000 -40000 RPM 3. It should have reverse and forward speed along. 4. It should have auto cut off system for over load. 5. It should be supplied with a. Hand piece (Autoclavable) : Speed : 40000 RPM b. Straight Hand Piece (Autoclavable): Speed 40000 RPM. **AIR COMPRESSOR:** 1. Medical grade, Oil free, Noise free at least 1 HP Compressor. 2. The compressor should be fitted with a. Built in thermo cut off to save motor during excess of heat b. auto head air release valve, c. Automatic cut off d. Safety release valve e. Drain Valve f. The inner surface of the compressor tank (at least 35 L) is coated with Epoxy to prevent rusting.

6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users on operation and basic maintenance.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential accessories, with their part number and cost.

11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

41. PORTABLE/MINI AUTOCLAVE (VACUUM TYPE)		
Version no.:		02
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		Sterilizing Units, Steam, Tabletop
GMDN code(s)		16142
GENERAL		
1. USE		
1.1	**Clinical purpose**	To sterilize medical devices.
1.2	**Used by clinical department/ward**	Emergency OT
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. The autoclave should provide sterilization at 121^{o} C and 134^{o} C for both wrapped and unwrapped tools and also a flash cycle for rapid sterilization. 2. The autoclave should be equipped with a powerful vacuum pump to eject air pockets from the chamber at the beginning and at the end of cycle (Pre-vacuum and Post vacuum) 3. It should have minimum four sterilization programs and two test programs. 4. Minimum volume at least 20 liters. 5. It should be class B autoclave so that hollow bodied instruments, hand pieces, and turbines can be fully autoclaved.
2.2	**User's interface**	Manual
2.3	**Software and/ or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Noise-free system

3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	NA
4. ENERGY SOURCE		
4.1	**Power requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	No
4.3	**Protection**	Stabilizer or inbuilt protection to voltage fluctuation/current surge.
4.4	**Power consumption**	To be specified by manufacturer.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	All accessories should be supplied to make equipment fully functional as per user requirement
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.

8.3	**Training of staff (medical, paramedical, technicians)**	Training of users on operation and basic maintenance.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential accessories, with their part number and cost.
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

42. **OPTHALMOSCOPE DIRECT**		
Version no. :		02
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Direct Ophthalmoscope
GMDN code(s)		46786
GENERAL		
1. USE		
1.1	Clinical purpose	Handheld ophthalmoscopes designed for examining the eye (mostly the back of the eye, the funds) by providing a non-inverted image of the eye.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Should have LED/halogen as light source. 2. Magnification up to x15 from direct vision to maximum magnification. 3. Red-free, blue and polarization filters and Anti-reflection lens. 4. Should have small and large spot sizes, fixation targets, slit aperture, hemi-spot and cobalt blue filter. 5. Should be rechargeable battery with Charger / battery/ mains operated. 6. Range of lenses not smaller than -30D to +20D with steps not greater than 1D. 7. Dust free sealed optics and aspherical optical system.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Portable
4. ENERGY SOURCE		
4.1	Power requirements	Rechargeable battery
4.2	Battery operated	Internal batteries, rechargeable preferred, Led

		display indicating the charging status.
4.3	Power consumption	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)	a. Bulb – 2 nos
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS	
6.1	Atmosphere/ambiance (air conditioning, humidity, dust …)	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity up to 90% in ideal circumstances
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer.
	7. STANDARDS AND SAFETY	
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
	8. TRAINING AND INSTALLATION	
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	Supplier to perform safety and operation check before handover
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation in basic maintenance shall be provided
	9. WARRANTY AND MAINTENANCE	
9.1	Warranty	3 years
	10. DOCUMENTATION	

10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets of : User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contract details of manufacturer, supplier and local service agent should be provided.
11.2	Recommendations or warnings	Any warnings should be adequately displayed.

43. OPTHALMOSCOPES, INDIRECT		
Version no. :		02
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Ophthalmoscopes, Indirect
UMDNS code(s)		12818
GENERAL		
1. USE		
1.1	Clinical purpose	Head-worn ophthalmoscopes designed for examining the eye (mostly the back of the eye, the fundus) by providing an inverted image of the fundus. These instruments usually consist of a light source attached to a headband to project the light into the eye through the pupil and a converging lens placed in front of the patient's eye.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Available with LED/Halogen light source. (Desirably LED). 2. Magnification up to 5x. 3. Red-free, blue and polarization filters. 4. Should have stereo optical system with small pupil feature. 5. Should have synchronized adjustment of convergence parallax.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (wherever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	Light weight
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Portable
4. ENERGY SOURCE		
4.1	Power requirements	NA
4.2	Battery operated	Rechargeable batteries
4.3	Protection	NA
4.4	Power consumption	NA

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	a. Three pencils, b. Fundus chart, c. Sclera depressor, d. 20D condensing lens with anti-reflecting coating. e. Bulb – 2 nos, Bulb holder, Bulb cover.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	Capable of continuous operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	03 years
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost
11. Notes		

11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

44. SLIT LAMP		
Version no. :		02
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		-
GMDN Code		-
GENERAL		
1. USE		
1.1	Clinical purpose	Ophthalmic diagnostic instruments designed for examining the eye (mostly the anterior part of the eye) using an illumination system combined with a binocular microscope. Slit lamps are used mainly in the diagnosis of eye conditions.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Should have LED with adjustable and good illumination. 2. Should have facility for applanation tonometer if required. 3. Type of microscope: Binocular 4. Should have 3 step magnification and total magnification is greater than 10x. 5. Should have slit width ≥ 0-10 mm, adjustable. 6. Should have slit length ≥ 0-10 mm, adjustable. 7. Should have standard filters: Minimum: blue, green (red-free), heat absorption. A broader selection of filters increases the functionality of the slit lamp. 8. Rotation is between 0-180°. 9. Should be supplied with motorized table. 10. Should have a longitudinal movement of at least 90 mm. 11. Should have a lateral movement of at least 95mm. 12. Should have a vertical movement of at least 30mm. 13. Should have a chin rest vertical movement of at least 55mm.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (wherever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	<50 dB

3.4	Heat dissipation	NA
3.5	Mobility, portability	NA
4. ENERGY SOURCE		
4.1	Power requirements	220 +/- 10% VAC, 50 Hz
4.2	Battery operated	Should be supplied with suitable online UPS with at least half an hour backup.
4.3	Protection	NA
4.4	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Focusing Test rod & dust cover. 2. Slit lamp dust cover, 3. Rack, manual and motorized guard, 4. 90D/70D Lens
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. DOCUMENTATION		

10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams. 2. Advanced maintenance tasks documentation. 3. Certificate of calibration and inspection, 4. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any warning sign should be adequately displayed.

45. RETINOSCOPE		
Version no. :		02
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Retinoscopes
UMDNS code(s)		23679
GENERAL		
1. USE		
1.1	Clinical purpose	Retinoscopy is a technique to obtain an objective measurement of the refractive error of a patient's eyes. The examiner uses a retinoscope to shine light into the patient's eye and observes the reflection (reflex) of the patient's retina.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Available with LED light source. 2. Should be interchangeable to plane mirror and concave mirror mode by sleeve movement. 3. Should have an external focusing sleeve which is easy to grip. 4. Should have crossed-linear polarizing filter. 5. Should allow one-hand operation for streak focus. 6. Available with 360º streak rotation. 7. Should have 100% dust proof housing and multi-coated optics.
2.2	User's interface	Manual
2.3	Software and/ or standard of Communication (wherever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	<50 dB
3.4	Heat dissipation	NA.
3.5	Mobility, portability	Portable
4. ENERGY SOURCE		
4.1	Power requirements	Rechargeable battery
4.2	Battery operated	Yes, should be rechargeable battery with Charger.
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		

5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Should have a carrying case. 2. Bulb – 2 nos 3. Rechargeable battery – 1 no
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	/Atmosphere/Ambiance (air conditioning, humidity, dust …)	Should be rugged and capable of withstanding operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

46. **KERATOMETER**		
Version no.:		02
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Ophthalmometers
UMDNS code(s)		12811
GENERAL		
1. USE		
1.1	Clinical purpose	Ophthalmic measuring instruments designed for objectively determining the curvature of the anterior corneal surface and the refraction of the eye (e.g., diopter, cylinder axis) by projecting illuminated images onto the patient's cornea. The instruments usually consist of light sources, a pair of objects to be projected onto the cornea, a telescope with prisms and lenses for reflecting and observing images, a device for adjusting the positions of the reflected images, and the software appropriate to calculate the corneal curvature and the refractive power. Ophthalmometers are used mainly for pre assessment for refractive corneal surgery and for contact lens fitting.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Should have (15x / 10x) eye piece. 2. Should measure corneal refractive power measuring range from 36 to 52 D in steps of 0.25D steps. 3. Should measure corneal radius of curvature measuring range from 6.5 to 9.4 mm in steps of 0.05mm. 4. Should have high accuracy of measurements. 5. Should have dust cover and spare bulb. 6. Should be supplied with motorized table. 7. Should have well illuminated circular mires with + sign.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	NA
4. ENERGY SOURCE		
4.1	Power requirements	220 +/- 10% VAC, 50/60 Hz single phase

4.2	Battery operated	No
4.3	Protection	NA
4.4	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Lamp (12v 10w): 5 No 2. Calibrating Device – 1 No
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	Requirements for sign- off	Supplier to perform installation, safety and operation checks before handover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. DOCUMENTATION		

10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Certificate of calibration and inspection, 4. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any warning sign should be adequately displayed.

47. AUTO REFRACTOMETER		
Version no. :		02
Date:		August 2023
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Refractometers
UMDNS code(s)		15169
GENERAL		
1. USE		
1.1	Clinical purpose	To auto calculate a patient's refraction error for prescription of glasses.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Should have in the system. 2. Should have refractive measurement sphere from -25 to +22D in steps of 0.25D. 3. Should have refractive measurement cylinder from -10 to +10D in steps of 0.25D. 4. Should have refractive measurement axis angle from 1 to 180º in steps of 1º. 5. Should have at least 0, 12 and 13.5 vertex distance. 6. Should measure a minimum pupil diameter of 2.5mm. 7. Should have at least 5 inches LCD/LED display. 8. Should have vertically adjustable chin rest of at least ±25mm. 9. Should have motorized table.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (wherever required)	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Table Top
4. ENERGY SOURCE		
4.1	Power requirements	220 +/- 10% VAC, 50/60 Hz
4.2	Battery operated	No
4.3	Protection	NA
4.4	Power consumption	To be specified by manufacturer.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		

5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Calibrating Device – 1 No.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	• 03 years • Preventive Maintenance visits at least once in each quarter
10. DOCUMENTATION		

10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams. 2. Advanced maintenance tasks documentation. 3. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

48. APPLATION TONOMETER		
Version no. :		02
Date:		August 2023
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Ophthalmic tonometer's, Applanation
UMDNS code(s)		10168
GENERAL		
1. USE		
1.1	Clinical purpose	Ophthalmic tonometer's designed to determine intraocular pressure by measuring the force required to flatten the cornea apex by a fixed amount. These instruments are typically small and reusable instruments and are attached to a slit lamp; the tono meter includes a tip to be applied to the cornea and a manually controlled spring that applies a variable force on the cornea through the tip.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Range of Measurement 0-80 mmHg 2. Movement of Light Circle 1.53 x 2 = 3.06mm 3. Prism Diameter 7mm 4. Prism Range of Movement 3mm 5. Should be compatible with all models of slit lamps.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise Free System
3.4	Heat dissipation	NA
3.5	Mobility, portability	Portable
4. ENERGY SOURCE		
4.1	Power requirements	NA
4.2	Battery operated	No
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		

5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Calibration Bar, 2. Prism 3. Tonometer Mount base to fix with optics.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	Capable for continuous operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	To be specified by manufacturer
8.2	Requirements for sign- off	Supplier to perform installation, safety and operation checks before handover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	03 years
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams. 2. Certificate of calibration and inspection.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any warning sign should be adequately displayed.

49. PHACOMACHINE		
Version no. :		02
Date:		August 2023
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Phaco emulsification Units, Cataract Extraction
UMDNS code(s)		17596
GENERAL		
1. USE		
1.1	Clinical purpose	Ophthalmic surgery units designed for removal of cataractous lenses by the insertion of a probe that cuts and emulsifies the lenses using ultrasonic waves (phacoemulsification). These units consist of a hollow probe (i.e., a phaco probe) that includes an irrigation sleeve, an oscillating tip that converts electric energy into ultrasonic waves, and a channel for aspiration of lens fragments; the units also include a vacuum pump and controls for the output levels, irrigation rate, and mode of operation. Phacoemulsification units are used in ophthalmic offices for cataract extraction surgery.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	**1. OPERATIONAL MODES:** i. System should have following operation modes: Irrigation, Ultrasound, Irrigation/Aspiration (I/A) system, Diathermy and Vitrectomy. **2. ULTRA SOUND SYSTEM:** i. Hand Piece type: Piezoelectric, made up of Titanium. ii. Frequency: 25-80 kHz. iii. It should be autoclavable. **3. IRRIGATION/ASPIRATION (I/A)SYSTEM:** i. System should have dual pump (Peristaltic and Venturi) user can switch between the two pumps during surgery with Max. Vacuum (peristaltic: 500 mmHg) with 1 mmHg pump increment. ii. Reflux method: Gravity / Pump reversal. iii. Tubing shall be re usable. iv. I/A Hand pieces shall be autoclavable with port diameter of 0.2-0.5 mm. v. Collection container size shall be 1-60 cc. **4. ANTERIOR VITRECTOMY:** i. Guillotine type hand piece with variable speed shall be preferred. ii. Hand piece shall be re usable and autoclavable. iii. Control Panel or linear cut rate control by foot pedal.

2.2	User's interface	Manual
2.3	Software and/ or standard of Communication (where ever required)	As Applicable.
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise Free System
3.4	Heat dissipation	Should maintain nominal temperature and the heat should disbursed through a cooling mechanism.
3.5	Mobility, portability	Mobile
4. ENERGY SOURCE		
4.1	Power requirements	220 +/- 10% VAC, 50/60 Hz
4.2	Battery operated	An UPS with 30 minutes back up shall be provided.
4.3	Protection	Stabilizer to be provided.
4.4	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Phaco hand piece – 1no 2. Phaco tips -4 nos 3. Anterior vitrectomy packs including cutters and other disposables – 25 nos 4. Cassettes and disposables – 12 nos.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	Should be capable of withstanding operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	Sterilization is required for hand piece, tips and forceps.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover.

8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams. 2. Certificate of calibration and inspection, 3. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any warning sign should be adequately displayed.

50. SUCTION MACHINE-FOOT & ELECTRIC OPERATED		
Version no. :		02
Date:		August 2023
Done by: (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		-
GMDN code		-
GENERAL		
1. USE		
1.1	Clinical purpose	To aspirate fluids, secretions, or other foreign materials from a patient's airway by means of suction
1.2	Used by clinical department/ ward	Emergency, ICU, OT, HDU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1.Should be designed for draining blood and other fragmented secretions in emergency settings. 2. Should be operable both electrically and foot operated during non-availability of electricity. 3. Should be fitted with oil immersed noiseless motorized vacuum pump. 4. Cabinet should be made of stainless steel (MS-304). 5. Should have two lightweight, clear glass or unbreakable polycarbonate Jar on the top having minimum capacity of 2 Ltr each fitted with rubber airtight lids and having overflow safety device. 6. Should have a motor of minimum ½ HP capacity single phase 1440 RPM with control knob. 7. Should have vacuum at least between 100 mmHg to at least 575 mm Hg ± 10 regulable with vacuum control knob. 8. Should be mounted on 4 castor wheels, nylon material, heavy duty, movable in all directions.
2.2	User's interface	Manual
2.3	Software and/or standard of communication (wherever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	Light weight
3.3	Noise (in dBA)	Noise free operation
3.4	Heat dissipation	NA
3.5	Mobility, portability	Yes

4. ENERGY SOURCE		
4.1	Power Requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.3	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)	Collection bottles, clear unbreakable jar (one set extra)
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust...)	Should be rugged and capable of withstanding operation in extreme and ambient temperature (10 deg C to 50 deg C). Capable to work in relative humidity up to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	Certifications	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover.
8.3	Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	• 03 years • Preventive Maintenance visits at least once in each quarter
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams.
10.2	Other accompanying documents	NA

11. NOTES		
11.1	Service Support Contact details (Hierchy Wise; including a toll free/landline number)	Contact details of manufacturer should be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared.

51. LARYNGOSCOPE		
Version no. :		02
Date:		August 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Laryngoscopes
GMDN code		CT1723
GENERAL		
1. USE		
1.1	**Clinical purpose**	For viewing vocal folds and glottis. Resuscitation, Surgical and mechanical ventilation/ intubation.
1.2	**Used by clinical department/ward**	PICU/NICU, OT, EMR, ICU/HDU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Fiber optic Laryngoscope - preferably should be reusable using the latest LED technology. 2. The main body of the handle should incorporate an excellent grip & should feel even wearing a glove. 3. The light source should light when the blade is placed into the operating position. 4. The unit should allow the blade to be inserted easily & should provide a positive locking mechanism when moved into the closed position. 5. Should have handle with universal adapter for interchangeable blades. 6. The laryngoscope should be supplied in leather/hard case preferably high impact plastic with internal soft cushion material for easy portability and protection. 7. The blades should be re-usable and autoclavable preferably made of S/Steel (MS-304) of high quality.
2.2	**Settings**	NA
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	Light weight
3.4	**Noise (in dBA), heat dissipation**	NA

3.5	**Mobility, portability**	Portable
	4. ENERGY SOURCE	
4.1	**Power Requirements**	NA
4.2	**Battery operated**	Yes
4.3	**Protection**	NA
4.4	**Power consumption**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables / reagents (open, closed system)**	Batteries, blades of various neonatal sizes Handle 5 LED should be given as spare
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Should be capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Should be autoclavable
	7. STANDARDS AND SAFETY	
7.1	**Certificates**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	NA

9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	03 years ; LED up to 6 months
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams.
10.2	**Other accompanying documents**	NA
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	Contact details of manufacturer and supplier should be provided..
11.2	**Recommendations or warnings**	Any recommendations for best use and supplementary warning for safety should be declared

52. DEFIBRILLATOR		
Version no. :		02
Date:		August 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	**Clinical purpose**	To provides an electric shock to heart to allow it to get out of a potentially fatal abnormal heart rhythm, or arrhythmia, — ventricular tachycardia (with no pulse) or ventricular fibrillation — and back to a normal rhythm.
1.2	**Used by clinical department/ward**	Emergency/ICU/Cardiac care
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Unit should be lightweight compact and portable. 2. Unit should have facility for Automatic External Defibrillation and manual defibrillation. 3. Should be able to deliver shock from 50-200 joules in biphasic mode via metal chest pads. 4. Should having design protection to avoid passage of current to the user. 5. The whole system should have an inbuilt recorder.
2.2	**Settings**	Manual and Automatic
2.3	**User's interface**	The monitor should have LCD display with a three-channel display.
2.4	**Software and/or standard of communication (wherever required)**	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Compact
3.2	**Weight (lbs, kg)**	<10kg
3.4	**Noise (in dBA), heat dissipation**	<60dBA; adjustable heart rate alarm as well as paddles & ECG cable disconnection alarms.
3.5	**Mobility, portability**	Yes
4. ENERGY SOURCE		
4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	Rechargeable battery backup of approximately 5 hours.
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by manufacturer

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables / reagents (open, closed system)**	Chest paddles ECG cable; Recording paper rolls; Disposable pads;
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Should be capable to withstand operation in extreme and ambient temperature (-10deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certifications**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Satisfactory certificate for any existing installation from

		government hospital
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost.
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any recommendations for best use and supplementary warning for safety should be displayed.

53. TRANSPORT VENTILATOR		
Version no. :		02
Date:		August 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Intensive-care ventilators
GMDN code(s)		CT2175
GENERAL		
1. USE		
1.1	**Clinical purpose**	To provide automated, alveolar ventilatory support for patients during interhospital or intrahospital transport, and in emergency situations. It is typically a compact, lightweight, rugged device with internal batteries to power it during patient transport.
1.2	**Used by clinical department/ ward**	Emergency /Critical Care.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1.Modes of ventilation: a) Volume controlled. b) Pressure controlled. c) Pressure support. d) Synchronized intermittent mandatory ventilation (SIMV). e) Assist/control mode. f) PEEP. 2. Alarms required: FiO2, minute volume, pressure, PEEP, apnoea, occlusion, high respiration rate, disconnection. 3. System alarms required: power failure, gas disconnection, low battery, vent inoperative, self-diagnostics. 4. If alarm silencing feature is incorporated, it must be temporary and clearly displayed when activated. 5. Air and externally supplied oxygen mixture ratios fully controllable. 6. Inlet gas supply (O2) pressure range at least 35 to 65 psi. 7. Medical air compressor integral to unit, with inlet filter. 8. Visual and audible alarms Accessories and tubing should be supplied for adult, pediatric & neo-natal size requirements.
2.2	**Settings**	The following variables should be controllable by the operator: a) Tidal volume up to 100 ml. b) Pressure (inspiratory) up to 80 cm H2O. c) Volume (inspiratory) up to 120 l/min. d) Respiratory rate: up to 60 breaths per minute. e) SIMV Respiratory Rate: up to 40 breaths per

		minute. f) PEEP up to 20 cm H2O. g) Pressure support up to 45 cm H2O. h) FiO2 between 21 to 100 %. i) Inspiratory and expiratory times up to at least 2 sec and 8 sec respectively.
2.3	**User's interface**	Manual and Automatic.
2.4	**Software and/or standard of communication (wherever required)**	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA), heat dissipation**	<60dB; Alarm > 65dB
3.4	**Mobility, portability**	Yes
4. ENERGY SOURCE		
4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	With at least 6 hours battery backup.
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by manufacturer
1. ACCESSORIES, SPARE PARTS AND CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables / reagents (open, closed system)**	Full face mask, breathing circuit, carry bag, filters Battery, leakage adapter.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Should be capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	**Certifications**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.

		5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Electrical sockets; Oxygen supply.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning signs would be adequately displayed.

54. ULTRASONIC NEBULIZER		
Version no. :		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Aerosol Generators
GMDN code(s)		10046
GENERAL		
1. USE		
1.1	**Clinical purpose**	Devices designed to produce (i.e. generate) gaseous suspensions of extremely small particles of a liquid or solid. These generators typically include a micro-ultrasonic or pneumatic pumping mechanism capable of creating a fine-particle liquid mist appropriate for delivery to the patient's airways and/or lung disposition
1.2	**Used by clinical department/ ward**	All
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.2	**Technical characteristics (specific to this type of device)**	1) Should be light weight, portable, compact and easy to use. 2) Frequency of ultrasonic generator should be greater than 1.5 MHz 3) Speed nebulization rate control (minimum, medium, maximum). 4) Should have a nebulisation capacity of 0.3 ml/min. 5) Transducer element should have life of at least 5000 hours. 6) Medication cup capacity should have capacity of maximum 8ml. 7) Should uses water as ultrasonic conduction medium, no gel is required. 8) Should provide silent operation. 9) Should have a built-in timer and shuts off after 10 minutes use.
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE		
4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	Should have in built rechargeable battery. Recharge should be possible with direct mains supply

4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables/reagents (open, closed system)**	Should be provided with a complete nebulization kit of 10 no's including adult.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust...)**	Should be capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type)**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hardcopy) of: - 1) User, technical, maintenance and service manuals should be supplied in English/Hindi/Regional language along with machine diagrams. 2) List of equipment and procedures required for local calibration and routine maintenance 3) Service and operation manuals (original and copy) to

		be provided. 4) Satisfactory certificate for any existing installation from government hospital
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning signs would be adequately displayed.

55. ECG MACHINE – 12 CHANNEL		
Version no. :		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Electrocardiographs, multichannel
GMDN code(s)		11411
GENERAL		
1. USE		
1.1	**Clinical purpose**	Continuously detect, measure and display a patients echocardiogram (ECG) through leads and sensors attached to the patient.
1.2	**Used by clinical department/ ward**	All
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.2	**Technical characteristics (specific to this type of device)**	1) Simultaneous 6 Channel ECG recording with 12 lead simultaneous acquisition. 2) Should have a digital display of 6 channel ECG and should have three modes (Automatic, Manual and rhythm). 3) Heart rate measurement range to be at least 30 bpm to 250 bpm, with accuracy better than ± 5bpm. 4) Heart rate trend display of at least previous 24 hours. 5) Arrhythmia detection facility required; minimum gradation of 1 bpm.
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication**	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	Less than 5 Kgs
3.3	**Noise (in dBA)**	< 50dB
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Portable.
4. ENERGY SOURCE		
4.1	**Power Requirements**	220V ± 10%, 50 Hz
4.2	**Battery operated**	Battery powered, silence able alarm for power failure. Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit. Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure.

4.3	**Protection**	Voltage corrector/stabilizer to allow operation at ± 30% of local rated voltage.
4.4	**Power consumption**	To be specified by manufacturer
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables/reagents (open, closed system)**	12 lead ECG cable. 2 sets of spare fuses (if non-resettable fuses are used) 5 tube electrode gel (if required)
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust...)**	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..);** **Performance and safety standards (specific to the device type)**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hardcopy) of: - 1) User, technical, maintenance and service manuals should be supplied in English/Hindi/Regional language along with machine diagrams. 2) List of equipment and procedures required for local

		calibration and routine maintenance. 3) Service and operation manuals (original and copy) to be provided.. 4) Satisfactory certificate for any existing installation from government hospital
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part numbers and cost
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning signs would be adequately displayed.

56. OT TABLE		
Version no. :		02
Date:		August 2023
Done by : (name / institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Operation table
GMDN code		NA
GENERAL		
1 USE		
1.1	**Clinical purpose**	An operating table, sometimes called operating room table, is the table on which the patient lies during a surgical operation.
1.2	**Used by clinical department/ward**	Operation theatre
TECHNICAL		
2 TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1) Should have OT Table type base made of high quality 304 stainless steel with double table, split leg type and can take x ray photography. 2) Should have imported Y type sealing ring with good sealing performance and durability. 3) Should have a Rotary brake device which is easy for moving operating table. 4) Base is stainless steel. 5) Leg board is separated & dischargeable. 6) Double-decked can-do X- Ray. 7) Inclining forward ≥30° 8) Inclining backward ≥25° 9) Inclining leftward≥20° 10) Inclining rightward≥20° 11) Back board folding upward ≥45˚ Fold downward ≥90° 12) Headboard folding upward ≥80°Folding downward ≥10° 13) Leg board Folding downward ≥90°. 14) Fold outward ≥90°. 15) Waist board elevation ≥120°. 16) The table top must be made of durable radiolucent Bakelite material capable of withstanding exposure to frequent C-Arm imaging, without diminishing the image clarity
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Max: Length:2050 ±50 mm Width:480 ±20 mm Height:750-950 ±50 mm

3.2	**Weight (lbs, kg)**	Max: 150 Kg (excluding battery)
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Stationary
4 ENERGY SOURCE		
4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	Yes
4.3	**Protection**	Should have over-charging cut-off with visual symbol.
4.4	**Power consumption**	To be specified by manufacturer
5 ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)**	1) Shoulder support (1 pair) 2) Waist Support (1 pair) 3) Arm rest (1 pair) 4) Leg holder (1 pair) 5) Screen Frame (1 Piece) 6) Foot Plate (1 Pair)
6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
7 STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type);Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8 TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users on operation and basic maintenance.
9 WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter
10 DOCUMENTATION		

10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hardcopy and soft-copy) of:- 1) User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams. 2) Advanced maintenance tasks documentation; 3) Certificate of calibration and inspection
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost;
11 NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning signs would be adequately displayed

57. Autoclave HP Horizontal		
Version no. :		02
Date:		August 2023
Done by : (name / institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Autoclave HP Horizontal
GMDN code(s)		NA
GENERAL		
1 USE		
1.1	Clinical purpose	An airtight vessel for heating and sometimes agitating its contents under high steam pressure; used for sterilizing, with moist or dry heat at high temperatures.
1.2	Used by clinical department/ward	CSSD
TECHNICAL		
2 TECHNICAL CHARACTERISTICS		
2.1	Technical Specifications	1) High Grade strong stainless steel, Triple walled construction. 2) Positive radial self-locking safety doors. 3) Hydrostatically tested to withstand 2.5 times the working pressure. 4) Sealed with Neoprene/Silicon long-lasting and durable gasket. 5) Digital display for Jacket and Chamber pressure and temperature. 6) Outer jacket insulated to prevent heat loss; with a high-grade insulation material 7) Mounted on 304 stainless steel frames with ground leveling flanges. 8) Temperature and pressure cut-off device. 9) Auto cut-off at low water level 10) Rust-proof 304 grade stainless steel. 11) Cylindrical construction. 12) Equipment should have separate steam release valve and drainage system. 13) Minimum of two safety valves with auto-release at 16 and 20.
2.2	**User's interface**	Manual
2.3	**Software and/ or standard of communication(where ever required)**	NA
3	**3 PHYSICAL CHARACTERICSTICS**	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA

3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	NA
	4 ENERGY SOURCE	
4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	No
4.3	**Protection**	Should have over-charging cut-off with visual symbol.
4.4	**Power consumption**	To be specified by manufacturer
4.5	**Operating Temperature**	121 deg C to 134 deg C
	5 ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)**	1. Automatic Pressure Control Switch -2 no. 2. Automatic Water Cut-off Device -2 no. 3. Micro Processor PID Controller with Timer & Auto Stop Facility 4. Digital Pressure Indicator-2 no. 5. Perforate basket(rust-free stainless steel) 6. Cord-plug-4 no. 7. Biological and chemical indicators-1 set
	6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Should be capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
	7 STANDARDS AND SAFETY	
7.1	**Certificates (pre- market, sanitary, ..); Performance and safety standards (specific to the device type);Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
	8 TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.

8.3	**Training of staff (medical, paramedical, technicians)**	Training of users on operation and basic maintenance;
9 WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter
10 DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hardcopy and soft-copy) of:- 1) User, technical and maintenance manuals to be supplied in English/ Hindi language along with machine diagrams. 2) Advanced maintenance tasks documentation. 3) Certificate of calibration and inspection
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost;
11 NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning signs would be adequately displayed

58. ANAESTHESIA WORKSTATION		
Version no. :		02
Date:		August 2023
Done by: (name. Institution)		HCT/NHSRC
NAME AND CODING		
UMDNS name		Anesthesia Units
UMDNS code(s)		10134
GENERAL		
1 USE		
1.1	Clinical purpose	Devices that continuously or intermittently administer a mixture of gases (e.g., oxygen, nitrous oxide, the vapor ofa volatile liquid such as halogenated hydrocarbon), varying the proportion of gases in order to control an individual's level of consciousness. These devices are also designed to facilitate spontaneous, controlled, or assisted ventilation with these gas mixtures. An anesthesia unit is typically comprised of four basic subunits: a gas supply and control circuit, breathing and ventilation circuit, a scavenging system to help prevent the escape of exhaled gases, and a set of function and breathing circuit monitors (e.g., inspired oxygen concentration, breathing circuit integrity).
1.2	Used by clinical department/ward	Operation Theatre
TECHNICAL		
2 TECHNICAL SPECIFICATIONS		
2.1	Technical characteristics (specific to this type of device)	**Flow Management:** 1. Should be compact, ergonomic and easy to use. 2. Machine should provide electronic gas mixing. 3. Multi color TFT display of at least 15"size, with virtual meters for O2, N2O or Air. 4. Dual flow sensing capability at inhalation and exhalation ports. 5. Should have backup 02 control which provides an independent fresh gas source and flow meter control in case of electronic failure. 6. Gas regulators (flow control valves) shall be of modular design/ graphic display. 7. All pipeline connections should have diameter-indexed safety systems (DISSs) or another means of preventing connection of dangerous gases. 8. System should permit connection of at least two yokes, one dedicated to 02 cylinder to meet clinical needs during failure of pipeline supply. All cylinder yokes (regardless of the gas for which they are intended)

		should include pin-index safety systems to prevent connection of dangerous gases. i. Hypoxic guard to ensure minimum 25% 02 across all 02-N2O mixtures and Oxygen failure warning. **Breathing System:** 1. Latex free fully autoclavable/ disposable with minimal flow of 250 ml of 02. 2. Sensor should not require daily maintenance. 3. Bag to vent switch shall be bi stable and automatically begins mechanical ventilation in the ventilator position. 4. Adjustable pressure limiting valve shall be flow and pressure compensated. **Vaporizers:** 1. Provision to mount following selectable vaporizers such as Desflurane, halothane, isoflurane, sevoflurane with interlocking facility to allow use of only one vaporizer at a time. 2. All the vaporizers should be temperature, pressure and flow compensated vaporizers and maintenance free. **Ventilation:** 1. The work station should have integrated anesthesia ventilator system. 2. It should have following Ventilation modes Manual/spontaneous, VCV, PCV, SIMV or pressure support, advanced modes. 3. Tidal volume: A control adjusts the volume of individual breaths within range of 20-1,500 cc. 4. Minute volume: A control adjusts the total inspiratory volume- per-minute delivery from the bellows shall be >20 L/min. 5. The respiratory frequency can be set within range of 5-60 breaths per minute. 6. Inspiratory flow: The flow range of gas that the ventilator is capable of delivering to the patient shall be 0-180 L/min. 7. Pressure limit shall be adjustable and <70 preferred cm H2O. Unit should have PEEP of 0-20 cm H2O. 8. The workstation should be capable of delivery of low flow anesthesia. **Anesthesia Monitoring Specifications:** 1. Monitoring of vital parameters: ECG, NIBP, SPO2, and Invasive Blood Pressure.

		2. Twin temperature measurement with skin and core temperature probes — Two sets with each monitor. 3. Automatic identification and measurement of anesthetic agents EtCO2, 02, and N2O and MAC value. FiO2 measurement. 3. Facility to store snapshots during critical events for waveform review at a later stage. 4. Audio visual and graded alarming system. **Display of Ventilator:** Mode of ventilation to be displayed, Respiratory rate, flow, pressure also to be displayed.
2.2	User's interface	Manual
2.3	Software and/ or standard of Communication (where ever required	Inbuilt
3 PHYSICAL CHARACTERICSTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise pressure level: <60 dbA.
3.4	Heat dissipation	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	Mobility, portability	Stationary
4. ENERGY SOURCE		
4.1	Power	220 +/- 10% VAC, 50 Hz
4.2	Battery operated	Yes, at least 30 minutes back up.
4.3	Protection	Stabilizer to be provided for protection.
4.4	Power consumption	To be specified by service provider.
5 ACCESSORIES, SPARE PARTS AND CONSUMABLES		

5.1	Accessories, standard, optional); Spare parts (main ones); Consumables/re- agents (open, closed system)	1. Cylinders/Pipeline 2. Circle absorber — 01 No. 3. Vaporizer Halothene — 01 No. 4. Vaporizer Desflurane — 01 No. 5. Vaporizer isoflurane — 01 No. 6. Vaporizer sevoflurane — 01 No. 7. Adult and Pediatric autoclavable silicone breathing circuits —2 each. 8. Reusable IBP cable -04. 9. Humidifiers — 1 No 10. Disposable transducer — 100 11. Temperature Probe Skin reusable — 02. 12. Temperature core reusable -04 (02-Adults, 02-paediatrics) 13. Depth of anesthesia sensors — 50 14. Accessories for neuromuscular transmission monitor - 01 set. 15. Standard accessories to make all parameters working - 01 set. 16. Disposable adult and pediatric circuit — 50 each. 17. HME Filters — 1000 nos 18. Vital parameter accessories (ECG Leads — 5 sets, NIBP Cuffs all sizes) -01 set. 19. Spo2 probes both adult and pediatric 2 in no should be supplied with each machine. 20. EtCo2 sampling line and connector should be supplied 25 no each with apparatus.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust . ..)	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	**To be specified by manufacturer**
7 STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8 TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up handover.

8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover..
8.3	Training of staff(medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	• 03 years • Preventive Maintenance visits at least once in each quarter
10 DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/ Regional language along with machine diagrams.; 2. Service and operation manuals(original and Copy) to be provided; 3. Advanced maintenance tasks documentation; 4. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11 NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

59. **ANAESTHESIA MACHINE**		
Version no. :		02
Date:		August 2023
Done by: (name. Institution)		HCT/NHSRC
NAME AND CODING		
UMDNS name		Anesthesia Units
UMDNS code(s)		10134
GENERAL		
1 USE		
1.1	Clinical purpose	Anesthesia machine is used for delivering anesthesia agents to the patients during surgery.
1.2	Used by clinical department/ward	Operation Theatre
TECHNICAL		
2 TECHNICAL CHARACTERICSTICS		
2.1	Technical characteristics (specific to this type of device)	1. Should be portable stainless steel, with large antistatic sturdy castor wheels fitted with brakes. 2. Anesthesia machine should be with 3 gas supply system (02, N2O and Air) with pipeline connections and reserve cylinder yokes. 3. All pipeline connections should have diameter-indexed safety systems (DISSs) or another means of preventing connection of dangerous gases. 4. System should permit connection of at least two yokes, one dedicated to 02 cylinder to meet clinical needs during failure of pipeline supply. All cylinder yokes (regardless of the gas for which they are intended) should include pin-index safety systems to prevent connection of dangerous gases. 5. Provision to mount following selectable vaporizers such as Desflurane, halothane, isoflurane, sevoflurane with interlocking facility to allow use of only one vaporizer at a time. All the vaporizers should be maintenance free. 6. It should have following Ventilation modes Manual / spontaneous, VCV. 7. Tidal volume: A control adjusts the volume of individual breaths within range of 50-1,200 cc. Minute volume: A control adjusts the total inspiratory volume-per-minute delivery from the bellows shall be >20 L/min. The respiratory frequency can be set within range of 5-60 breaths per minute. 8. Inspiratory flow: The flow range of gas that the ventilator is capable of delivering to the patient shall be 0-120 L/min. 9. Pressure limit shall be adjustable and <70 preferred cm H2O. 10. Unit should have PEEP of 0-20 cm H2O.

		11. Unit can able perform to ensure proper functioning of Pre-use vent, gas supply, ongoing system. 12. It should have active or passive scavenging system. 13. It should provide facility to monitor of Airway pressure along with High-pressure alarm, Sub atmospheric pressure alarm, continuing pressure alarm and low pressure/apnea. 14. System should also provide facility to monitor of expiratory volume/ flow along with Apnea alarm. 15. It should have 3 (caution, advisory, alarm) prioritized alarms for ventilator failure, low oxygen supply pressure, inadequate volume delivery, disconnecting alarm and power supply failure. 16. Should have dual cascade type flow meter for 02, N2O and Air calibrated in multiple scale. 17. Should have adjustable pressure limiting valve, breathing circuit pressure measuring device. 18. Should have a bag/ ventilator select valve integrated on to absorber. 19. Should be able to use low flow anesthesia technique and facility to attach oxygen sensor. 20. Should have CO2 absorbent chamber canister. 21. Integrated physiological monitoring is preferred.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	Inbuilt
3 PHYSICAL CHARACTERICSTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise pressure level: <60 dbA.
3.4	Heat dissipation	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	Mobility, portability	NA
4. ENERGY SOURCE		
4.1	Power	220 +/- 10% VAC, 50 Hz
4.2	Battery operated	Yes, at least 30 minutes back up.
4.3	Protection	Stabilizer to be provided for protection.
4.4	Power consumption	To be specified by manufacturer
5 ACCESSORIES, SPARE PARTS AND CONSUMABLES		

5.1	Accessories, standard, optional); Spare parts (main ones); Consumables/re- agents (open, closed system)	1. Should have a provision for mount monitors on top of the machine. The table top made up of stainless steel/ chemical resistant fiber 2. Standard bains circuit: 2 nos. with each unit 3. Humidifier — 1 no 4. Vaporizer Halothene — 01 No. S. Vaporizer Desflurane — 01 No. 6. Vaporizer isoflurane — 01 No. 7. Vaporizer sevoflurane — 01 No. 8. Reservoir bag (2liters): 3 nos. with each machine 9. Connectors for bains circuit: 5 nos with each machine. 10. AMBU bag: 1 no. with each machine. Pressure regulated valve with 5 meter hose and connector (conversion kit) for oxygen should be provided with each machine. Should be supplied with driver gas hoses with necessary attachments (color coded).
6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	Should be capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND MAINTENANCE		
8.1	Pre- installation requirements:	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	• 03 years • Preventive Maintenance visits at least once in each quarter
10. DOCUMENTATION		

10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/ Regional language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Advanced maintenance tasks documentation;, 4. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying Documents	List of essential spares and accessories, with their part number and cost;
11. NOTES		
11.1	Service Support Contact details	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

60. ELECTROSURGICAL UNIT		
Version no. :		02
Date:		August 2023
Done by: (name. Institution)		HCT/NHSRC
NAME AND CODING		
UMDNS name		Electrosurgical Unit
UMDNS code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	Diathermy uses an electric current to produce heat deep inside a targeted tissue. It can reach areas as deep as two inches from the skin's surface. The diathermy machine does not apply heat directly to the body. Instead, the current from the machine allows the body to generate heat from within the targeted tissue
1.2	Used by clinical department/ward	OT
TECHNICAL		
2. TECHNICAL CHARACTERICSTICS		
2.1	Technical characteristics (Specific to this type of device)	1) Facility for Monopolar, Bipolar and underwater cutting. 2) Monopolar cutting and coagulation 3) Micro-processor-based technology 4) Monopolar cut in minimum 3 modes 5) Bipolar coagulation in 3 or more modes (forced coagulation, spray coagulation and soft coagulation) 6) Blending of cutting and coagulation -in minimum 2 levels 7) Automatic cut-off technology with self check on every start. 8) Foot and hand switch 9) Auto monitoring and display of set parameters 10) Touch-controlled interface to set parameters 11) 4 or more programmable memory 12) Simultaneous use of Monopolar and Bipolar Coagulation. 13) Output Power of 300 Watt(Minimum) 14) Monopolar Cutting and Coagulation power adjustable from 0-300 Watt 15) Bipolar Coagulation power adjustable from 0-50 W, Micro Power Range- 0.1-to-9.9-Watt increment of 0.1 Watt, Macro Power range from 1-50 Watt increment of 1 Watt 16) Audio-Visual Alarm for disconnection of Neutral Plate
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	Inbuilt
3. PHYSICAL CHARACTERICSTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA

3.3	Noise (in dBA)	Noise pressure level: <60 dbA.
3.4	Heat dissipation	NA
3.5	Mobility, portability	Portable
4. ENERGY SOURCE		
4.1	Power	220 +/- 10% VAC, 50 Hz
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	To be specified by Manufacturer
5. ACCESSORIES, SPARE PARTS AND CONSUMABLES		
5.1	Accessories, standard, optional); Spare parts (main ones); Consumables/re- agents (open, closed system)	1) Power cord :1pc 2) Electrode lever:1pc 3) Electrode:2sets 4) Collective electric bulb: 2pcs switch 5) Trolley;Foot switch 6) Reusable electrode handle with cutting/coagulation switch 7) Disposable REM plate 8) Cable for electrode handle 9) Neutral plate for adults and pediatric
6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND MAINTENANCE		
8.1	Pre- installation requirements:	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover.
8.3	Training of staff(medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.

9. WARRANTY AND MAINTENANCE		
9.1	Warranty	• 03 years • Preventive Maintenance visits at least once in each quarter
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1) User, technical and maintenance manuals should be supplied in English/Hindi/ Regional language along with machine diagrams. 2) Advanced maintenance tasks documentation; 3) Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying Documents	List of essential spares and accessories, with their part number and cost;
11. NOTES		
11.1	Service Support Contact details	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

61. RADIANT WARMER		
Version no. :		02
Date:		August 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	**Clinical purpose**	Infant Radiant warmer is an electrically powered device with a radiant heating source intended to maintain the thermal balance of an infant by direct radiant of energy in the infrared region of the electromagnetic spectrum.
1.2	**Used by clinical department/ ward**	Neonatal ICU/ SNCU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. It should be microcontroller chip based radiant warmer with manual and servo options. 2. It should have the facility to display skin set, skin observed temperature in degree C and heat power separately. 3. Should have user friendly touch panel control. 4. It should have ceramic or quartz infrared or calrod heater. 5. It should have audiovisual alarm facility for overheating beyond set temperature range. 6. It should have alarm facility for patient temperature less than or greater than the required temperature i.e. above or below the set range. Machine should sense the skin probe failure and cut off the heater. 7. The warmer head should be rotatable in different direction, so as to allow taking X-ray. 8. It should have an alarm for probe failure, power failure, system failure and heater failure. 9. Observation light of 90 to 100 foot candles or 1000 Lux (color temperature range 3700K to 5100K) should be provided for inspection 10. Battery backup for Power failure indication during power fail. 11. The desired temperature range from 25 to 40 degree C and settable temperature can be from 32 to 38 degC. 12. The resolution should be 0.1 degree C and accuracy should be 0.2 °C. 13 Should have a facility to lock the keyboard to avoid

		unwanted user modification of the set parameters. 14. The height of the warmer should be adjustable for different types of bed. 15. It should have separate bassinet trolley, bed should be tiltable and have provision for x-ray cassette holder, Mattress foam density should be minimum 25 kg/cm3, transparent collapsible side walls easily detachable for cleaning. Mattress size should be minimum 20"X30". 16. Should have a Feather Touch operation with large digital display and comprehensive alarms. Control Panel should be liquid proof and allow easy and hygienic disinfection. 17. Manual Mode can adjust Heater Output 10 -100 %, with 10% increment, an auditory and visual alarm shall be given at least every 15 min. 18. In manual mode, heater cut off / switch off, if the maximum irradiance at any point of the mattress area exceeds a total irradiance level of 10 mW/ cm2 (between 10 to 30 minutes). 19. Bed should be about 80 - 100 cms from the Floor and 80-90cms from the heat source. 20. Should have lockable castor wheels. 21. Green indicator light shall be provided to indicate that warmer is ready for normal use. 22. Markings on the bassinet and X-Ray cassette holder is mandatory to enable proper positioning of the baby while doing the X-Ray. 23. The size of the drop-down sides should be such that it is 5" above the mattress surface and should be at least 6mm thick; clear and transparent. 24. If there is more than 60% heater output for 10 minutes it should cutoff with alarm. 25. For the purpose of cable management there should be at least two number of tubing ports (edges covered by silicon rings) on the side walls. The height of the side walls should be minimum 110mm over the mattress. 26. X-Ray cassette tray should be at least 750X350mm and should adopt up to 20mm thick X-Ray cassette. 27. The bay bed should be crevice free for ease of cleaning, infection control. 28. The mattress used should be of biocompatible material. 29. Thermistor based skin temperature probe should be small in size not more than 10mm diameter and 3-4mm thick to fix the probe firmly on the infant. Baby contact material should be biocompatible as per ISO 10993 standard requirement. It should be insulated on one side and have well conducting non-rusting, non-reacting metallic surface on the other side. Probe wire should be pliable, thin and soft. The attachment site of the probe

		with the wire should also be pliable and non-stiff.
2.2	**Settings**	1. Should have Manual mode and Baby (Servo) mode settings. 2. Mode of operation should be clearly displayed. 3. In servo mode baby set temperature should be 32 to 38 deg C.
2.3	**User's interface**	Manual and Servo controlled temperature regulation.
2.4	**Software and/or standard of communication (where ever required)**	LED Display and inbuilt software; Interruption and restoration of the power supply does not change the preset values.
2.5	**Others**	1. Device shall not overbalance when placed in any transport position of normal use on a 10° inclined plane from the horizontal plane. 2. Transformers of device shall be protected against overheating in the event of short circuit or overload of any output winding. 3. Patient leakage current should be less than 100 µA in normal condition. 4. Temperature on the baby mattress should not exceed 43 deg C when the warmer is operating under steady temperature condition. 5. Temperature of HEATER GUARDS should not exceed 85 °C in normal use. 6. The Temperature differences on the mattress shall not exceed 2 °C.
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	maximum spec: 150kg.
3.4	**Noise (in dBA)**	Sound level of the alarm shall not exceed 80 dBA
3.5	**Heat dissipation**	Should maintain up to 36.5 deg temp and the heat disbursed through a exhaust fan, so that effect of UV light is not disturbed.
3.6	**Mobility, portability**	Mobile
4. ENERGY SOURCE		
4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	± 10% input
4.4	**Power consumption**	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables /**	Should have standard IV pole(sturdy; on rusting; medical grade stainless steel; adjustable to a max height of 6 feet from the ground level), monitor tray(12X10 inches;270 deg swivel; fixed at level of warmer display) and storage trays. Skin temperature probes,

	reagents (open, closed system)	Thermal reflector to fix the skin probe on baby.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Performance and safety standards (specific to the device type); Certificates (pre-market, sanitary, ...); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost
11. NOTES		

11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning/ precautions to be declared

62. PULSE OXIMETER-TABLE TOP		
Version no.:		02
Date:		August 2023
Done by: (name / institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Pulse oximeter
GMDN code(s)		45607
GENERAL		
1. USE		
1.1	**Clinical purpose**	It is used for the transcutaneous measurement and display of haemoglobin oxygen saturation (SpO2). The signals are produced by light-emitting diodes (LEDs) and received by a photodetector. The device displays the SpO2 values and may also measure and display pulse rate.
1.2	**Used by clinical department/ward**	All Departments
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Should be a portable, light weight, desktop model with adult, pediatric and neonatal finger probes. • Should have digital display with parameters: SpO2, pulse rate, plethysmograph waveform, alarm message and battery state indication. • SpO2 detection range to include: 70–100% • SpO2 resolution: 1% or less • Accuracy of SpO2 should be within +/-3% • SpO2 probes should be reusable. • Pulse rate range detection range to include: 30-240 beats per minute (bpm). • Pulse rate accuracy: within ± 3 bpm. • Pulse rate resolution: 1 bpm or less • Audio and visual alarms required: high and low SpO2 and pulse rate (operator variable settings), sensor disconnected, sensor failure, low battery. • Suitable for detection in low perfusion conditions.

		• Should have a minimum of 02 hours back-up time. • Should have trend data of at least 36 hrs.
2.2	**User's interface**	Digital display and easily accessible buttons to operate the machine.
2.3	**Software and/or standard of communication (wherever required)**	In built.
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	Light weight
3.3	**Noise (in dBA)**	<60dBA
3.4	**Heat dissipation**	Should be dispersed through exhaust.
3.5	**Mobility, Portability**	Mobile
4. ENERGY SOURCE		
4.1	**Power Requirements**	220 V +/- 10% AC, 50 Hz
4.2	**Battery operated**	Yes, with minimum backup time of 02 hour
4.3	**Power consumption**	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories & Spares parts; Consumables / reagents (open, closed system)**	Two reusable probes each for adult, pediatric and infant use
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
7. STANDARDS AND SAFETY		

7.1	**Certifications**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards in case of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Electrical accessories as per standard Indian set-up
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 4. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 5. List of equipment and procedures required for local calibration and routine maintenance. 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	NA
11. NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.

11.2	**Recommendations or warnings**	Any recommendations for best use and supplementary warning for safety should be displayed.

63. **BOWL STERILIZER**		
Version no. :		02
Date:		August 2023
Done by : (name / institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Bowl Sterilizer(big)
GMDN code		NA
GENERAL		
1 USE		
1.1	**Clinical purpose**	Used for the purpose of sterilizing various medical instruments.
1.2	**Used by clinical department/ward**	Operation theatre
TECHNICAL		
2 TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1) Constructed of high-grade stainless steel. 2) For steam sterilization/disinfection of utensils, bowls etc. 3) Low water cut off device 4) Fitted with thermostat 5) With perforated inner chamber 6) Water outlet with angle iron painted stand. 7) Sterilizer tank is made of stainless-steel SS 304 8) The perforated Tray of SS 304 is provided for keeping the Bowls of different size for sterilization. 9) Three SS heaters of 1.5 KW each for sterilization 10) Outer Cabinet is heavy gauge SS 304 11) Double walled with glass wool insulation. 12) Digital PID temperature controller for controlling the temperature. 13) Digital time controller housed in Temperature controller cabinet used for exposure time control. 14) Level Control give audible signal for maximum water level
2.2	**User's interface**	Manual
2.3	**Software and/ or standard of communication(where ever required)**	NA
3 PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA

3.5	**Mobility, portability**	NA
4 ENERGY SOURCE		
4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	NA
4.3	**Protection**	Should have over-charging cut-off with visual symbol.
4.4	**Power consumption**	To be specified by manufacturer
5 ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)**	NA
6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
7 STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type);Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign- off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users on operation and basic maintenance.
9 WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter
10 DOCUMENTATION		

10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets(hardcopy and soft-copy) of:- 1) User, technical and maintenance manuals to be supplied in English/ Hindi language along with machine diagrams; 2) Service and operation manuals (original and copy) to be provided.
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost;
11 NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning signs would be adequately displayed

64. TABLE FOR OBSTETRIC LABOUR (LDR)		
Version no.:		02
Date:		August 2023
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		Birthing Bed/Table, Powered
GMDN Code		15732
GENERAL		
1. USE		
1.1	Clinical Purpose	Table for Obstetric labour (LDR) is specifically designed to support the mother during all stages of giving birth that includes labour, delivery and recovery. The bed should convert quickly from a practical labour bed to a delivery platform and back to a comfortable recovery bed. At any stage, it can be rapidly adjusted to any positions to cater for emergency situations.
1.2	Used by clinical departm ent/ward	Labour Room Complex (As per Labour room standard Guideline)
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical Characteristics (Specific to this type of device)	1. The LDR bed should be electro-mechanically controlled. 2. It should have three sections and seamless joint in each part with minimal gap between sectional mattresses and the seat-section should have a large perineal cut. 3. Mattresses cover should be non-slippery, washable and waterproof. 4. The foam density of the mattresses should be of minimum 60 kg/m^3 and thickness of minimum 3-4 inches. 5. The mattress should be fixed with high grade adhesive velcro tape for proper fixing on the bed top. 6. Removable SS (304)/ABS head and leg bows with padded panel. 7. The unit should have provision for trendelenburg and reverse trendelenburg positions (minimum 15 degree or more) and reclinable adjustable back rest angle of 60 degree or more. All positions should be achievable both mechanically and electronically. 8. Should have control device for back and height adjustments through remote control as well as manually operable. 9. Pre-fitted SS-304 grade adjustable/collapsible side rails. 10. Push grip handle (grab bars) with soft cushion padding on both sides of the bed. 11. Should have foot support for nursing staff.

		12. Frame should be of epoxy powder coated steel. 13. Should be easy to clean, sterilize (especially blood stains) and maintain. 14. Should have catheter bag holder which can be attached on either side of bed. 15. Should have infusion rods (made of SS-304 grade) which have adjustable heights, quick release and attachable to all corners of the bed. 16. Should have retractable foot section (section can be telescoped under) so as to convert bed into table. 17. To and fro motion of the leg section should be very smooth. 18. Should be able to hold minimum 150 Kg of load. 19. Caster: Should have minimum 100mm or more heavy duty roller wheels with ball bearing and with central & directional locking mechanism. 20. Should have rectangular sliding/detachable SS-304 tray at perineal part of table.
2.2	User's Interface	Electro-mechanical.
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (in mm)	Overall approximate size 1880 -2160 mm (L) * 900 - 1010 mm (W) * 550 mm to 880 mm (H) (With option of manual adjustable height of the bed)
3.2	Weight	To be specified by the Manufacturer/Supplier
3.3	Noise	Less than 50 db.
3.4	Heat Dissipation	Not applicable
3.5	Mobility/Portability	Area Specified above (Labour room)
4. ENERGY SOURCE		
4.1	Power input	220-240V AC,50 Hz fitted with Indian plug
4.2	Battery backup	1. Battery backup of minimum 30 minutes operation time with inbuilt battery charger shall be provided. The handset shall have indications for power on and battery charge. 2. Should have facility to operate manually in case of power failure.
4.3	Power consumption	To be specified by the Manufacturer/Supplier
4.4	Protection	Overcurrent breaker must be present
5. ACCESSORIES, SPARE PARTS AND CONSUMABLES		
5.1	Accessories, (mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system)	1. All consumables required for installation and standardization of the system should be provided free of cost. 2. Minimum 60 mm thick kg/m^3 high density foam mattress washable and waterproof and detachable in three parts. 3. Should be provided with extra one pair of leg rest. 4. Should be provided with minimum four infusion rods (SS 304) with hook for hanging IV fluids.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		

6.1	Atmosphere /Ambiance (air conditioning, humidity, dust ...)	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer
	7. STANDARDS & SAFETY	
7.1	Certificates (pre-market, sanitary,..);Performance and safety standards (specific to the device type);Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
	8. TRAINING AND INSTALLATION	
8.1	Pre-installation requirements: nature, values, quality, tolerance	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover.
8.3	Training of staff (medical, paramedical, technicians)	Hands on training to be provided to healthcare professional on using the equipment, day to day maintenance/cleaning.
	9. WARRANTY AND MAINTENANCE	
9.1	Warranty	• 03 years • Preventive Maintenance visits at least once in each quarter
	10. DOCUMENTATION	
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hardcopy and soft-copy) of: - 1. User manuals to be supplied in English/Regional language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Service and operation manuals (original and copy) to be provided.

10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations and Warnings	Appropriate warning sign/labels should be adequately displayed on the LDR Bed.

65. 300 mA X-Ray		
Version no. :		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		**300 mA HF X-Ray machine**
GMDN code		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	Medical x-rays are used to generate images of tissues and structures inside the body.
1.2	**Used by clinical department/ ward**	Radiology
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	High Frequency X-Ray machine suitable for general Radiography. **X-Ray Generator** • High Frequency X-Ray generator having Frequency of 40 KHz more suitable for Radiography should be provided. • Power output of generator should be 25 KW or more. • Radiography KV range should be 40 to 110 KV or more. • mA range (Rad.): 300mA or more • Exposure time (Rad.): 1 ms to 2 sec. with maximum numbers of steps. **Control:** • A very compact, Soft Touch Control Panel having following functions & indications should be provided. The panel can be supplied in floor or wall mount with Spill Proof design Following features should be available on the control panel. • Machine ON/OFF switch • Digital Display of KV& mAs. • K V & mAs increase and decrease switches. • Tube focal spot selection switch. • Ready and x-ray on switch with indicators. • Bucky Selection switch. • Self diagnostic Programme with Indicators for Earth fault error, KV error, filament error & Tube's Thermal Overload. **X-Ray Tube** • One No Dual focus Rotating Anode thermally protected having focal spot: • 1mm or less small Focus, 2mm or less large Focus. • Anode heat storage capacity of tube should be more than 140 KHU. • One no manual collimator with aluminum filter & for adjustment of exposure area.

		Column Stand: • It should have floor to ceiling stand with vertical counter balanced travel. • It should have 360 deg. Rotation. • It should be provided one vertical bucky stand with machine. • Table. • Five position manual tilt table having bucky grid ratio of 8:1 with 85 lines per inches should be provided. • The bucky tray should accept cassette of 8”x10”, 10”x12” and 14”x17” size.
2.2	**User’s interface**	Manual
2.3	**Software and/or standard of communication (where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Noise-free system
3.4	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism
3.5	**Mobility, portability**	Certified Room Installation
4. ENERGY SOURCE		
4.1	**Power Requirements**	Input voltage- 380V-440V AC, 50Hz ;3-phase
4.2	**Battery operated**	No
4.3	**Protection**	Stabilizer of appropriate capacity to be installed.
4.4	**Power consumption**	To be certified by manufacturer.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)**	Machine should be supplied with following: I. 2 No. BARC Approved whole body lead aprons with all attachments. II. One Pair of 8 meter H. V. Cable.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User’s care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO and AERB approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.

8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	1) Availability of three phase uniform power supply. 2) Safety and operation check before handover. 3) To be installed in a separate room.
8.2	**Requirements for sign-off**	Certificate of calibration and inspection of parts from the manufacturer.
8.3	**Training of staff (medical, paramedical, technicians)**	1) Training of users on operation and basic maintenance. 2) Advanced maintenance tasks required shall be documented;
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hardcopy and soft-copy) of: 1) User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams. 2) List of equipment and procedures required for local calibration and routine maintenance. 3) Service and operation manuals (original and copy) to be provided. 4) Advanced maintenance tasks documentation. 5) Certificate of calibration and inspection. 6) Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part numbers and cost;
11. NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning signs would be adequately displayed.

66. PORTABLE ULTRASOUND		
Version no. :		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Ultrasound system
GMDN code		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	Diagnostic sonography (ultrasonography) is an ultrasound-based diagnostic imaging technique used for visualizing internal body structures including tendons, muscles, joints, vessels and internal organs for possible pathology or lesions. The practice of examining pregnant women using ultrasound is called obstetric sonography and is widely used.
1.2	**Used by clinical department/ ward**	Radiology laboratories
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1		**Ultrasound scanner with integrated trolley with probe, soft touch alphanumeric keyboard with track ball:** 1. With panel switches & control's easily operable. 2. Integrated high resolution Monitor (17"). 3. Probes & Gel holder-conviniently placed (2 each). **Following transducers are to be supplied:** 1. A-2.0-5.0 MHz Multi frequency Convex Transducer-One. 2. B-5.0-12.0 MHz Multi frequency Linear transducer-One. 3. C-5.0-8.0 MHz or more Endo Cavitory probe-One. **(+/- 1 MHz to be allowed for each):** a. All probes should be electronic transducers and multi-frequency preferably three frequencies and should give aperture & depths of scanning. b. Controls for Depth, gain compensation, body markers with transducers position. c. Real-time continuous dynamic focus. d. Auto annotation facility anywhere on image. e. Image display in B, B/M&M Model(2B&2D). f. Zoom facility minimum five times or more. g. Shades of grey 256 h.Inbuilt cine memory.

		h. Unite should be capable of measuring BPD, CRL, FL & AC and other GA parameters. i. Facility for image magnification, inversion, changing, scan, direction, freeze facility. j. 8 step STC/GTC should be available. k. Frame rate minimum 50 FPS, hard disk capacity of 200GB or more. l. Caliper with trackball for the measurement of distances circumferences, area volume etc. should be possible to make different measurement on single image. m. Alphanumeric keyboard, Panel Switches & Foot Controls. n. Patient reports for Obs/Gynae including fetal growth trend, including Histogram facility for Tissue texture & Trend graph for IUGR cases, Urology and orthopedics. o. Give the gain adjustable/Range & its steps. p. Calculations needed, Velocity, Heart rate, Volume addl. modes. q. Dicom 3.0 compatible. r. Review of stored images is desirable. s. Channels: 1000 or more. t. Depth: 25 to 30 cm. u. Dynamic range: 170dB & above. v. Cine loop preivew for minimum 60 secs or more. w. Minimum 2 active ports should be there.
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication(where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Mobile
4. ENERGY SOURCE		
4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	No
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		

5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)**	The system should be supplied with the following accessories: 1. B & W thermal printer with 50 rolls. 2. Two KVA online suitable UPS.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up Machine to be installed only when PCPNDT registration is obtained by health care facility.
8.2	**Requirements for sign-off**	Certificate of calibration and inspection from the manufacturer
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users on operation and basic maintenance
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hardcopy and soft copy) of: 1) User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams. 2) Service and operation manuals (original and copy) to be provided. 3) Advanced maintenance tasks documentation. 4) Satisfactory certificate for any existing installation from government hospital.

10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost;
11. NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning signs should be adequately displayed.

67. CELL COUNTER AUTOMATIC (5 PART)		
Version no. :		02
Date:		August 2023
Done By (Name/Institution		HCT/NHSRC
NAME AND CODING		
GMDN name		Haematological Cell Analyser IVD
GMDN code(s)		35476
GENERAL		
1. USE		
1.1	**Clinical purpose**	An automated laboratory instrument intended to be used for the enumeration of a haematological cell population, using technology to measure and calculate white cell, red cell and platelet parameters and indices in a clinical specimen.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Five-part differential with reticulocyte count based on the principle of flow cytometry including minimum 24 parameters with two histograms and scattergrams for RBC and PLT: BASO, WBC, LYM, MON, NEU, EOS, BAS, LYM%, MON%, NEU%, EOS%, BAS%, RBC, HCT,MCV, RDW-SD, RDW-CV, HGB, MCH, MCHC, PLT, PCT, MPV, PDW-SD, PDW-CV. • Advanced, integrated self-cleaning system. • Stores minimum 25,000 test results with histograms and scattergrams. • Sample Material - EDTA blood with atleast pre-diluted mode and whole blood mode. • Integrates with common practice management systems including cleaning of apertures, tube systems and calibration. • Should be able to perform all parameters on variable sample volume for adult and pediatric patients. • Should be able to avoid micro-RBCs interference in platelet count. • System must have throughput of atleast 60 or more samples per hour. • Should be equipped with automatic sample loading, mixing and testing. Also have manual mode and STAT modes along with Random access for individual samples. • Open system • Pre-diluted mode and whole blood mode • QC Mode LJ, SD, CV, QC histogram. • Provision for bi-directional LIS interface should be available. • Provision for Bar Code/QR code reading should be

		available. • The equipment should have in-built digital display unit and PC interface facility.
2.2	**User's interface**	Touch screen and PC
2.3	**Software and/or standard of communication (wherever required)**	NA
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should bedisbursed through a cooling mechanism.
3.6	**Mobility, portability**	Stationary lab Installation.
	4. ENERGY SOURCE	
4.1	**Power Requirements**	220 +-10% VAC, 50 HZ
4.2	**Battery operated**	UPS System with minimum back up time of one hour.
4.6	**Protection**	N/A
4.7	**Power consumption**	As specified by the manufacturer
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open,closed system)**	2D-Barcode/QR Code Scanner. PC, Keyboard, Printer Reagents: All the reagents required for 1000 tests should be supplied with the equipment along with one set of tri level control.
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (airconditioning, humidity, dust ...)**	Operating condition: Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of up to 90% in ideal circumstances
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type);Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
	8. TRAINING AND INSTALLATION	

8.1	**Pre-installation requirements: nature, values, quality, tolerance**	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration 2. Preventive maintenance visits atleast one in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, servicemanuals, other manuals**	Should provide 2 sets (hardcopy and soft copy) of: 1) User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams. 2) List of equipment and procedures required for local calibration androutine maintenance. 3) Service and operation manuals (original and copy) to be provided. 4) Advanced maintenance tasks documentation. 5) Certificate of calibration and inspection;
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost;
11. NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landlinenumber)**	Contact details of manufacturer, supplier and local service agent to beprovided.
11.2	**Recommendations or warnings**	Any warning signs should be adequately displayed.

68. FULLY AUTOMATED BIOCHEMISTRY ANALYSER		
Version no.:		02
Date:		August 2023
Done by: (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Multichannel clinical chemistry analyser IVD, laboratory
GMDN code		56677
GENERAL		
1. USE		
1.1	**Clinical purpose**	An automated laboratory instrument intended to be used for the qualitative and quantitative in vitro determination of multiple clinical chemistry analytes in a clinical specimen. Analytes detected may include electrolytes, specific proteins, lipids and kidney, liver and/or cardiac function test analytes.
1.2	**Used by clinical department/ ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• The equipment should be capable of all Routine STAT and special Biochemical tests including specific protein, therapeutics, and user defined applications in clinical sample like whole blood, serum, plasma, urine and body fluids. • Throughput: minimum 200 tests/hour. • Measurement principle: photometric analysis. • Optical System should have Wavelength range from 340 to 700 nm. • Should have built in Cooled reagent Compartment with sample volume 2- 40 µl. • Auto diagnosis of machine errors with message and correction steps. • Must have on board capacity for permanent and numbered cuvettes. • Separate probe for reagents and sample. • Laundry System with minimum 5 step washing. • Minimum carryover of not more than 0.05 ppm. • The system should be having the facility of both auto-calibration and manual. • Should have solid state light source (LED Technology) with a split reference beam with working life of more than 10000 hrs. • Should have minimum 50,000 Patient Result memory Storage • Online QC Tracking with Levy and Jennings Chart for upto 30 different points, SD and CV.

		• Provision for Bar Code/QR code reading should be available. • The equipment should have in-built digital display unit and PC interface facility.
2.2	**User's interface**	• Digital display • Provision for bi-directional LIS/HIS interface should be available.
2.3	**Software and/or standard of communication (wherever required)**	Built - in/Automatic/compatible, window based with data processing management system with complete back up of data base for calibration,control, patient sample results on daily basis.
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should bedisbursed through a cooling mechanism.
3.6	**Mobility, portability**	Stationary lab Installation.
	4. ENERGY SOURCE	
4.1	**Power Requirements**	220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	UPS system with minimum one hour back up
4.4	**Protection**	NA
4.5	**Power consumption**	To be specified by manufacturer
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open,closed system)**	1. Suitable Water plant/Purification System on RO or any latest technology. 2. External printer. 3. UPS online pure sine wave for back up of system with PC and ITperipherals for one hour. 4. One light source.
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Operating condition: Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance andsafety standards (specific to the device**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.

	type);Local and/or international	4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements:nature, values, quality, tolerance**	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical,paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. 2. Preventive maintenance visits at least one in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, servicemanuals, other manuals**	Should provide 2 sets (hardcopy and soft-copy) of: - 1) User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams. 2) List of equipment and procedures required for local calibration androutine maintenance. 3) Service and operation manuals (original and copy) to be provided. 4) Advanced maintenance tasks documentation. 5) Certificate of calibration and inspection
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost;
11. NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a tollfree/landline number)**	Contact details of manufacturer, supplier and local service agent to beprovided.
11.2	**Recommendations or warnings**	Any warning signs should be adequately displayed

69. BINOCULAR MICROSCOPE		
Version no.:		02
Date:		August 2023
Done by: (name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		NA
GMDNS code(s)		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	A microscope is a laboratory instrument used to examine objects that are too small to be seen by the naked eye. Microscopic analysis of specimens helps diagnose diseases by looking at cellular morphology and presence of infectious agents and other microscopic structures. Binocular microscope is a microscope that lets the viewer use both eyes as it has 2 eye lenses.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Body-Single mold sturdy stand inclined Binocular body 30 °, 360º rotatable head without adjusting screws with inter-pupillary distance of 50-75mm. • It should have LED light source with rechargeable battery system. • Eyepieces-Paired high quality 10X/20mm wide angle anti fungus field eyepiece. one with pointer. Diopter adjustment must be present on both eye pieces. • Objectives-Parfocal, antifungal coated 4x, 10x, 40x and 100x having numerical aperture 0.1, 0.25, 0.60-0.65 and 1.25-1.65 respectively. Oil immersion objective (40x and 100x) should be spring loaded. All objectives should be plan achromatic, antifungal coated infinity and color corrected. Objective should be well centered even if their position on turret is changed. • Mechanical stag- ceramic coated surface with vernier scale on X-Y axis and slide holder. • Condenser, numerical aperture (NA) 1.25 focusable with rack and pinion arrangement incorporating spherical lens and iris diaphragm. It should have filter holder and swing in/out blue filter.

		• Should have inbuilt protective safety device which can withstand fluctuations of voltage from 140 V-280V. • LED illumination 3W with intensity control knob > 10,000 Hrs bulb lifespan with battery backup of 1 hrs and charging indication. • Focusing knob should have coaxial coarse and fine focusing knobs. Fine focusing movements should have sensitivity of 2 micron or less, coarse focus with torque adjustment, focusing stop for slide safety should be there.
2.2	**User's interface**	Manual
2.3	**Software and/ or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Stationary lab Installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	**Power Supply:** 220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	No
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by manufacturer/vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional);** **Spare parts (main ones);** **Consumables/reagents (open, closed system)**	Should be provided with wooden storage box, dust cover, immersion oil.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of up to 90% in ideal circumstances.

6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.

10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

70. **ISE BASED ELECTROLYTE ANALYSER**		
Version no.:		01
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		Ion-selective Analyser IVD
GMDN code(s)		56682
GENERAL		
1. USE		
1.1	**Clinical purpose**	A laboratory instrument intended to be used for the quantitative measurement of electrolytes and other ions in a clinical specimen using ion-specific membranes to selectively measure electrical potential against a reference electrode to determine the target ion concentration.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Should be able to measure sodium [Na+], potassium [K+], chloride [Cl-]). • Should be based on measuring method of Ion Selective Electrode (ISE) (Direct Potentiometer). • Should have individual electrodes for the electrolytes. • Should have automatic calibration. • Should have a throughput of minimum 40 samples per hour. • Should have a memory of at least 100 samples. • QC should be based on test parameters. • The equipment should have in-built digital display unit, PC interface facility and provision for printing of reports • Should have provision for barcode/ QR code reader.
2.2	**User's interface**	• Touchscreen Display • Provision for bi-directional LIS interface should be available.
2.3	**Software and/ or standard of communication (wherever required**	Inbuilt-To be provided by manufacturer
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Stationary lab installation
4. ENERGY SOURCE		

4.1	**Power requirements**	220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	Online UPS for minimum one hour back up
4.3	**Protection**	Internal electrical protection
4.4	**Power consumption**	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	1. 2D-Barcode/QR code Scanner. 2. Built-in Thermal printer or provision for external printer. 3. All the consumables, controls and calibrators and any other reagents or items required for conducting 1000 tests should be mentioned and supplied with the equipment. 4. Online UPS for minimum one hour back up
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of -10 to 60 deg C (minimum range) and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. 2. Preventive maintenance visits atleast once in each quarter
10. DOCUMENTATION		

10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Certificate of calibration and inspection, 5. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

71. COAGULATION ANALYZER		
Version no.:		01
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		Coagulation analyser IVD, laboratory
GMDNS code(s)		56689
GENERAL		
1. USE		
1.1	**Clinical purpose**	A laboratory instrument intended to be used for the qualitative and quantitative in vitro determination of one or multiple coagulation components involved in haemostasis in a clinical specimen (e.g., performs tests such as prothrombin time (PT), partial thromboplastin time (PTT))
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Blood Coagulation analyzer should be a fully automated (It should automatically aspirate, dispense, incubate and measure) with random access. • The system must be open for essential reagents. • Should have option for clotting, Chromogenic, turbidimetric, fluorogenic or immune assays as well. • Instrument should be able to detect automatically positive sample and reagent positions. • Possibility of auto rerun and auto redilution of samples should be available, positive sample and reagents level detection should be provided. • It should support a wide range of parameters including PT, APTT, Factor Assay, Protein C, Protein S, Fibrinogen, and Thrombin Time, ATIII, Heparin, PLG, LP(a), APCR, DDI, FDP, vWf. Factor VIII quantification. • Throughput: Must perform at least 20 tests (for APTT and PT) per hour. • Storage: It should have capacity of storing 1000 test results in its memory. • System should have on-board cooling facility to maintain the temperature of the reagents. • Machine should provide patient analysis curve.

		• Instrument should have in-built Barcode reader for identification of sample and reagents i.e. name, stability, volume, position etc. • System should have software that automatically generates LJ charts for QC and have appropriate alerts. • Provision for Bar Code/QR code reading should be available. • The equipment should have in-built digital display unit and PC interface facility.
2.2	**User's interface**	• LCD Display • Provision for bi-directional LIS interface should be available.
2.3	**Software and/ or standard of communication (wherever required)**	In built – to be provided by the manufacturer
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Stationary lab installation
4. ENERGY SOURCE		
4.1	**Power requirements**	**Power Supply:** 220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	UPS of suitable kVA with at least 1 hour backup.
4.3	**Protection**	Internal electrical protection.
4.4	**Power consumption**	To be specified by manufacturer/vendor.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional);** **Spare parts (main ones);** **Consumables/reagents (open, closed system)**	1. All the consumables, controls and calibrators and any other reagents or items required for conducting 500 tests should be mentioned and supplied with the equipment. 2. Barcode/QR code Scanner 3. Built-in Thermal printer or provision for external printer 4. Online UPS for minimum 1 hour back up
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of -10 to 60 deg C (minimum range) and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); Performance and**	1. Should be CDSCO approved. 2. Should comply with BIS standards.

	safety standards (specific to the device type); Local and/or international	3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	Compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 3 years, including all spares and calibration. • Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided. 4. Certificate of calibration and inspection, 5. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

72. Lower and Upper Extremity Cycle/Basic Ergometer/Static Cycle		
Version no. :		02
Date:		August 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Ergometer, Bicycle
GMDN code(s)		10383
GENERAL		
1. USE		
1.1	**Clinical purpose**	Aerobic cycle exercisers designed to simulate the motions of riding a bicycle; the bicycles remain stationary while the wheels move. These exercisers are usually self-powered devices; they may use friction belts or wheels, magnets, fans, or hydraulics to increase resistance. Some stationary bicycles may include a motor to regulate speed.
1.2	**Used by clinical department/ward**	Physiotherapy Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. LCD Display unit to measure heart rate, speed, distance, time and energy. 2. Should have a digital display showing speed, time, distance and calories used. 3 Body should be rugged and made up of SS-304 grade (Anti-Rust) 4. Should have comfortable saddle and foam fitted handle. 5. Should have an adjustable design to fit all heights and weights. 6. Should be able to bear body weight upto 100 kg. 7. Comfortable latex/Rubber hand grip facility for pulse oximetry. 8. Should have a resistance system with manual control. 9. Should have large adjustable softer HR seat 10. Should have firm, durable, broad paddle with adjustable locking strap.
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication (wherever required)**	In-built
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA), heat dissipation**	NA
3.4	**Mobility, portability**	NA
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	NA

4.3	**Protection**	NA
4.4	**Power consumption**	As specified by manufacturer
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory,standard, optional)** **Spare parts (main ones)** **Consumables / reagents(open, closed system)**	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance(air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterilityissues**	To be specified by manufacturer.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ...); Performanceand safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over.
8.3	**Training of staff (medical,paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	03 years
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, othermanuals**	User manuals to be supplied in English languagealong with machine diagrams.
10.2	**Other accompanying documents**	NA
	11. NOTES	
11.1	**Service Support Contactdetails (Hierchy**	Contact details of manufacturer and supplier should be provided.

	Wise; including a toll free/ landline number)	
11.2	**Recommendations or warnings**	NA

73. Ultrasound Therapy		
Version no.:		01
Date:		August 2023
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. Use		
1.1	**Clinical purpose**	Ultrasound therapy uses sound waves to penetrate soft tissues and is used by therapists to treat pain conditions and promote tissue healing.
1.2	**Used by clinical department/ ward**	Physiotherapy department
TECHNICAL		
2. Technical characteristics		
2.1	**Technical characteristics (specific to this type of device)**	1. The unit should have a LCD Screen and should deliver therapeutic ultrasound. 2. The unit should have variable frequency selector option for clinical supplication. 3. The unit should have pulse and continuous modes of ultrasound. 4. The unit should have variable duty cycles (10%, 20%, 50%, 100% etc.). 6. It should have predefined treatment protocols. 7. The ultrasound probe should be waterproof, sturdy and sensitive for effective skin penetration.
2.2	**User's interface**	LCD display
2.3	**Software and/or standard of communication (wherever required)**	Inbuilt
3. Physical Characteristics		
3.1	**Dimensions (metric)**	NA

3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dba)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
	4. Energy source	
4.1	**Power requirements**	220 V AC +/- 10%, 50 Hz
4.2	**Battery operated**	NA
4.3	**Power consumption**	To be specified by manufacturer
	5. Accessories, spare parts, consumables	
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)**	1. Ultrasound Head 2. Movable trolley
	6. Environmental and departmental considerations	
6.1	**Atmosphere / ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity up to 90% in ideal circumstances.
6.2	**User's care, cleaning, Disinfection & sterility issues**	To be specified by manufacturer
	7. Standards and Safety	
7.1	**Certificates (pre-market, sanitary, ..); performance and safety standards (specific to the device type); local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
	8. Training and Installation	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before handover

8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation in basic maintenance shall be provided
9. Warranty and Maintenance		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter
10. Documentation		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets of 1.User manual should be provided in English/ Hindi language along with the machine diagram 2. Service and operation manual should be provided.
10.2	**Other accompanying documents**	NA
11. Notes		
11.1	**Service support contact details (hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

74. Transcutaneous Electric Nerve Stimulator (TENS)		
Version no.:		01
Date:		August 2023
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		
GMDN code(s)		
GENERAL		
1. Use		
1.1	**Clinical purpose**	Transcutaneous Electric Nerve Stimulator (TENS) is used to provide a degree of symptomatic pain relief by exciting sensory nerves and thereby stimulating either the pain gate mechanism and/or the opioid system.
1.2	**Used by clinical department/ ward**	Physiotherapy Department
TECHNICAL		
2. Technical characteristics		
2.1	**Technical characteristics (specific to this type of device)**	1. It should be advanced microprocessor based and should have minimum 4 channels. All channels should be independent. 2. It should be compact, lightweight with a digital display of patient parameters. 3. It should have automatic intensity control to make it safe to operate. 4. It should have independent intensity control and a display of output current for each channel. 5. It should have a digital display of output current of each channel and treatment time. 6. The machine should produce output only after intensity of all channels are set to Zero. 8. Output current -0-60 mA 9. Output voltage 0-100V 10. Frequency 1-200 Hz 11. Pulse width 75-360 sec

		12. Treatment time- 5,10,15,20 minutes.
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication(where ver required)**	NA
3. Physical Characteristics		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	Light weight
3.3	**Noise (in dba)**	N.A.
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
4. Energy source (electricity, Ups, solar, gas, water, co2)		
4.1	**Power requirements**	220 V AC +/- 10%, 50 Hz
4.2	**Battery operated**	Yes
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by manufacturer
5. Accessories, spare parts, consumables		
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)**	Stimulation needles of various sizes
6. Environmental and departmental considerations		
6.1	**Atmosphere / ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, cleaning, Disinfection & sterility issues**	To be specified by manufacturer.
7. Standards and Safety		

7.1	**Certificates (pre-market, sanitary, ..); performance and safety standards (specific to the device type); local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. Training and Installation		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. Warranty and Maintenance		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter
10. Documentation		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided.
10.2	**Other accompanying documents**	NA
11. Notes		
11.1	**Service support contact details (hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

75. Flash Autoclave		
Version no.:		01
Date:		August 2023
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. Use		
1.1	**Clinical purpose**	Flash autoclave is used for routine sterilization of the instruments, also more suitable for emergency sterilization. This is widely used for various uses in the medical industries especially for eye, dental and laboratories for various sterilization purposes.
1.2	**Used by clinical department/ ward**	Operation Theatre
TECHNICAL		
2. Technical characteristics		
2.1	**Technical characteristics (specific to this type of device)**	1. Outer case of the unit should be made up of stainless steel (MS-304) and the unit should be based on microprocessor automatic system from adding water to sterilization and dry cycle. 2. Chamber capacity should be atleast 25 L or more. 3. Machine should perform pre and post vacuum functions. 4. Machine should have program selector to perform leakage, helix, prior preset test and the facility of internal water tank with auto chamber fill. 5. Machine should have emergency reset buttons and selectable dry time 0-60 min and have auto cut off feature for voltage surge protection. 6. Should have a low water indicator feature to indicate water status and to avoid overheating and digital display of temperature. 7. It should have a high vacuum ejector to ensure effective air removal for effective steam penetration and efficient post sterilization drying.

		8. Pressure auto door lock feature as a safety feature to avoid opening of the door when the processor is on. 9. USB port to print temperature, pressure and time of cycles.
2.2	**User's interface**	Automatic
2.3	**Software and/or standard of communication (wherever required)**	NA
3. Physical Characteristics		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dba)**	Noiseless
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Stationary
4. Energy source (electricity, Ups, solar, gas, water, co2)		
4.1	**Power requirements**	220 V AC +/- 10%, 50 Hz
4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.4	**Power consumption**	As specified by manufacturer
5. Accessories, spare parts, consumables		
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)**	NA
6. Environmental and departmental considerations		
6.1	**Atmosphere / ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, cleaning, Disinfection & sterility issues**	To be specified by manufacturer
7. Standards and Safety		

7.1	**Certificates (pre-market, sanitary, ..); performance and safety standards (specific to the device type); local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. Training and Installation		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. Warranty and Maintenance		
9.1	**Warranty**	03 years including all spares. Preventive maintenance visits at least once in each quarter.
10. Documentation		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Satisfactory certificate for any existing installation from government hospital
10.2	**Other accompanying documents**	NA
11. Notes		
11.1	**Service support contact details (hierchy Wise;**	Contact details of manufacturer, supplier and local service agent to be provided.

	including a toll free/landline number)	
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

76. ECG MACHINE – 6 CHANNEL		
Version no. :		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Electrocardiographs, multichannel
GMDN code(s)		11411
GENERAL		
1. USE		
1.1	**Clinical purpose**	Continuously detect, measure and display a patients echocardiogram (ECG) through leads and sensors attached to the patient.
1.2	**Used by clinical department/ ward**	All
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.2	**Technical characteristics (specific to this type of device)**	1) Simultaneous 6 Channel ECG recording with 12 lead simultaneous acquisition. 2) Should have a digital display of 6 channel ECG and should have three modes (Automatic, Manual and rhythm). 3) Heart rate measurement range to be at least 30 bpm to 250 bpm, with accuracy better than ± 5bpm. 4) Heart rate trend display of at least previous 24 hours. 5) Arrhythmia detection facility required; minimum gradation of 1 bpm.
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication**	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	< 60dB
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Portable.
4. ENERGY SOURCE		
4.1	**Power Requirements**	220V ± 10%, 50 Hz
4.2	**Battery operated**	Battery powered, silence able alarm for power failure. Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit.

		Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure.
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by manufacturer
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables/reagents (open, closed system)**	6 lead ECG cable. 100 sets of ECG connection electrodes (if disposable type). 5 sets of ECG connection electrodes (if reusable type). 2 sets of spare fuses (if non-resettable fuses are used) 5 tube electrode gel (if required)
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type)**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.

10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hardcopy) of: - 1) User, technical, maintenance and service manuals should be supplied in English/Hindi/Regional language along with machine diagrams. 2) List of equipment and procedures required for local calibration and routine maintenance. 3) Service and operation manuals (original and copy) to be provided.. 4) Satisfactory certificate for any existing installation from government hospital
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part numbers and cost
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning signs would be adequately displayed.

77. ECG MACHINE – 3 CHANNEL		
Version no. :		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Electrocardiographs, multichannel
GMDN code(s)		11411
GENERAL		
1. USE		
1.1	**Clinical purpose**	Continuously detect, measure and display a patients echocardiogram (ECG) through leads and sensors attached to the patient.
1.2	**Used by clinical department/ ward**	All
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.2	**Technical characteristics (specific to this type of device)**	1) Simultaneous 3 Channel ECG recording with 12 lead simultaneous acquisition. 2) Should have a digital display of 3 channel ECG and should have three modes (Automatic, Manual and rhythm). 3) Heart rate measurement range to be at least 30 bpm to 250 bpm, with accuracy better than ± 5bpm. 4) Heart rate trend display of at least previous 24 hours. 5) Arrhythmia detection facility required; minimum gradation of 1 bpm.
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication**	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	< 60dB
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Portable.
4. ENERGY SOURCE		
4.1	**Power Requirements**	220V ± 10%, 50 Hz
4.2	**Battery operated**	Battery powered, silence able alarm for power failure. Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit.

		Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure.
4.4	**Power consumption**	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables/reagents (open, closed system)**	3 lead ECG cable. 100 sets of ECG connection electrodes (if disposable type). 5 sets of ECG connection electrodes (if reusable type).
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type)**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. DOCUMENTATION		

10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hardcopy) of: - 1) User, technical, maintenance and service manuals should be supplied in English/Hindi/Regional language along with machine diagrams. 2) List of equipment and procedures required for local calibration and routine maintenance. 3) Service and operation manuals (original and copy) to be provided.. 4) Satisfactory certificate for any existing installation from government hospital
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part numbers and cost
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning signs would be adequately displayed.

78. Oxygen Therapy Equipment (High Flow Nasal Cannula)		
Version no. :		01
Date:		August 2023
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		Professional High Flow Respiratory Unit
GMDN Code		57828
GENERAL		
1. USE		
1.1	Clinical Purpose	**High flow nasal cannula** (**HFNC**) is an oxygen supply system capable of delivering up to 100% humidified and heated oxygen at a high flow rate required in ICU settings.
1.2	Used by clinical department/ward	ICU (Intensive Care Unit) and HDU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical Characteristics	HFNC unit consists of a mobile trolley with tubing and oxygen hose holding set (Basket/Drawer), servo controlled auto heated humidifier with accessories and power cable. The unit should have the features for treating paediatric and adult patients in a single unit. 1. Ability to generate flow from room air and mix with oxygen. Adaptable to all type of oxygen source. 2. The mixed gas of air and oxygen should be humidified and warmed between 31^0C – 40^0C. 3. FiO2: 21 to 100 % 4. Flow: 2 to 60 L/min with controls to adjust the flow rate. 5. Controls to be easy to operate, numbers and displays to be clearly visible. 6. Digital display of Temperature [°C], Flow [L/min], Oxygen concentration [%]. 7. Humidity compensation system. 8. Noise level to be less than 35 dB A at mid pressure range. 9. Trigger sensitivity range: 1-10 cmH2O, increments of 1 cmH2O or automatic. 10. All parts withstand high disinfection procedures

		11. Visual and audible alarm for: High/Low FiO2; Incorrect Temperature/Humidity; System leakage or blockage, lack of water, system failure, air filter to be replaced, power failure and low battery. 12. Display easily readable in low ambient light and sunlight. 13. Displayed parameters: Gas temperature (°C), FiO2 Tidal volume; Inspiratory pressure; Inspiratory and Expiratory time; I:E ratio; Mean Airway Pressure (MAP); Air leak [%]. 14. Machine should be installed on Mounting Tray and Pole with Castor C& IV Hook. 15. HNFC tubing and hose should be kink proof pliable material with option of adhesive pads to stick on skin for paediatric patients. Should have smooth bore tubing to minimise risk of kinking and should be noiseless in operation. 16. Should have a tracheostomy interface for use in tracheostomy patients.
2.2	User's Interface	User interface to be easy to operate, numbers and displays to be clearly visible.
3. PHYSICAL CHARACTERISTICS		
3.1	Design	1. Soft nasal prongs – silicone prongs for patient comfort. 2. Contoured nasal prongs – soft and anatomically formed nasal prongs conform to the individual patients to provide maximum patient comfort. 3. Should be metal free – safe to use in the MRI suite. 4. Universal connector – should be compatible with most heated wire breathing circuits. 5. Colour coded for quick and easy identification. 6. Secure connections – adjustable tube holder for eliminating drag and working in tandem with the lanyard and clip. 7. Adjustable tube replacement - detachable smooth bore tube and plug so that the tube can be comfortably placed on either side. 8. Split head strap design – easy to use wide elastic split strap for secure fit and patient comfort.
3.2	Dimensions (in cm)	Nasal prong of various sizes having standard diameter for use in pediatric and adult patient: Small: 4mm, Medium: 5mm, Large: 6mm
3.3	Weight	To be specified by the Manufacturer
3.4	Noise	NA
3.5	Heat Dissipation	NA
3.6	Mobility/ Portability	Should be light weight and easily movable with minimal physical effort.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)		

4.1	Power input	1. Operates from AC power electric line: 220-240 V, 50 Hz. Built-in rechargeable battery 2. Automatic switch from AC power electric-line mode to battery operating mode and vice versa.
4.2	Power consumption	To be specified by the Manufacturer/Supplier.
4.3	Battery backup	Continuous in battery operating mode withstands at least 1 hour.
5. ACCESSORIES. SPARE PARTS AND CONSUMABLE		
5.1	Accessories, (mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system)	HFNC should be supplied with accessories, consumables and parts required for its proper operation, which include: 1. Housing and patient interface for adult and paediatric use; withstands high level disinfection and sterilization. 2. Flowmeter, graduated in L/min 3. Humidifier 4. Water chamber 5. Connectors for air and oxygen outlets 6. Mains power cable ≥ 2 m
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere /Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of -10 to 60°C and relative humidity upto 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	As per manufacturer recommendations
7. STANDARDS & SAFETY		
7.1	Certificates (pre-market, sanitary);Performance and safety standards (specific to the device type);Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		

8.1	Pre-installation requirements: nature, values, quality, tolerance	HFNC system shall be installed and commissioned by qualified and skilled technician. Any prerequisites for installation to be communicated in advance.
8.2	Requirements for sign-off	1. Compliance with quantity checklist. 2. Complete quality check of the product.
8.3	Training of staff (medical, paramedical, technicians)	Hands on training to be provided to the end users on using the equipment, day to day maintenance/cleaning.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years including all spare parts and accessories.
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	1. Should provide two sets of hard copy and a soft copy of user, technical and maintenance manual printed in English/Hindi along with the diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and copy) to be provided; 4. Certificate of calibration and inspection from the factory by the manufacturer.
10.2	Other accompanying documents	Certification on quality of material of construction.
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	1. Contact details of manufacturer, supplier and local service agent to be provided. 2. Any Contract (AMC/CMC/ad-hoc) to be declared by the manufacturer. 3. Purchaser may engage third party for maintenance of equipment and vendor needs to comply in all terms. 4. Manufacturer/ Supplier of medical services should provide price quote for spare part of medical device or supply items, against requisition/Purchase order from Biomedical engineers/technicians.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed

79. Water Bath		
Version no. :		01
Date:		August 2023
Done by : (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Baths, Water
UMDNS code(s)		15108
GENERAL		
1. USE		
1.1	**Clinical purpose**	Baths used to increase, decrease, or hold constant the temperature of bodies or vessels immersed in the water.
1.2	**Used by clinical department/ward**	Clinical Lab
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Stainless Steel, insulated double walled. 2. Inner wall of stainless steel. 3. Temperature range from ambient to 100° C complete with immersion heater. 4. Aluminium /SS cover. 5. Brass drain cock. 6. Digital microprocessor display to set temperature point preventing thermal runaway. 7. Seamless reservoir with no welds to leak or rust, see-through cover should be removable.
2.2	**User's interface**	Manual
2.3	**Software and/ or standard of communication (wherever required**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Noise-free system
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism
3.5	**Mobility, portability**	Stationary
4. ENERGY SOURCE		
4.1	**Power requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	No
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		

5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	1 .Operating Condition: Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	03 years Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. Advanced maintenance tasks documentation; 3. Certificate of calibration and inspection, 4. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		

11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed.

80. Turbidometer		
Version no.:		01
Date:		August 2023
Done by : (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	**Clinical purpose**	The turbidimeter is an instrument used for measuring the turbidity of a liquid by determining the degree to which particles suspended in the solution decrease the intensity of light lost as a beam is passed through it.
1.2	**Used by clinical department/ward**	Clinical Lab
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Material should be of high-grade SS (MS-304) 2. Should be benchtop type with LED/LCD display. 3. Suitable for measurement even for colored samples. 4. Range- 0-1000 NTU in four ranges minimum. 5. Resolution should be 0.01 NTU or better. 6. Accuracy: +/- 2 percent of full scale 1 and 1000 NTU 7. The detector should be photodiode. 8. Should have tungsten lamp light source. The lamp life should be minimum for 1 Lakh readings. 9. Measuring modes – Normal, Average & Continuous. The range selection should be automatic. 10. Should be operable in both electric and re-chargeable batteries mode.
2.2	**User's interface**	Manual
2.3	**Software and/ or standard of communication (wherever required**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA

3.3	**Noise (in dBA)**	Noise-free system
3.4	**Heat dissipation**	Should maintain nominal temp and the heat should be disbursed through a cooling mechanism
3.5	**Mobility, portability**	Tabletop
4. ENERGY SOURCE		
4.1	**Power requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	Yes
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Should be supplied with cuvettes and cuvettes stand.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards in case of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements:**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.

	nature, values, quality, tolerance	
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years, including all spares and calibration. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. Service and operation manuals (original and Copy) to be provided; 3. Advanced maintenance tasks documentation; 4. Certificate of calibration and inspection, 5. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed.

81. AMBU BAG		
Version No:		02
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		-
GMDN code		-
GENERAL		
1. USE		
1.1	Clinical purpose	An Ambu bag, is a handheld tool used to provide ventilation (positive pressure) who is not breathing or who is breathing inadequately. It consists of a self-inflating bag, one-way valve, mask, and an oxygen reservoir.
1.2	Used by clinical department/Ward	Emergency department, Operation Theatre, Ambulance, Resuscitation kit.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Bag should be made up of silicone, latex free, double layered rubber and should retain sensitivity, resistant to rough use. 2. Inlet end of the bag should have separate port for oxygen supplement. 3. Outer port should be such that re-breathing valve or non-return valve can be attached. 4. Should be supplied with oxygen reservoir bag and should deliver tidal volume of 250/500/750 & 1000 ml. 5. Should be autoclavable. 6. Should be provided with a carry case.
2.2	User's interface	Manual
2.3	Software and/or standard of communication (wherever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	NA
4. ENERGY SOURCE		

4.1	Power Requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories (mandatory, standard and optional); spare parts (main ones) and Consumables/ Reagents (Open/Closed System)	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust...)	Should be capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	Autoclavable face mask
7. STANDARDS AND SAFETY		
7.1	Certifications (Pre-Market, Sanitary,), Performance and Safety Standards (Specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	03 Years
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: • User, technical and maintenance manuals should be supplied in English/Hindi/ Regional language along with machine diagrams.
10.2	Other accompanying documents	NA
11. NOTES		

11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer and supplier should be provided.
11.2	Recommendations or warnings	NA

82. Haemoglobinometer		
Version no. :		01
Date:		August 2023
Done by : (Name, Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	**Clinical purpose**	Haemoglobinometer is intended to be used for quantitative measurement of haemoglobin in fresh capillary or whole blood samples.
1.2	**Used by clinical department/ward**	Clinical lab, POC device
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. It should be an automated, integrated system and based on Photometry. 2. Open system (preferably) with direct read-out on LED/LCD display for estimation of hemoglobin. 2. Should have LCD display screen and auto shut off feature when not in use. 3. Should display results in g/dl. 4. Measuring Range 0 to 25 g/dl 6. Should have automatic calibration system for maintaining accuracy of reading (<5%CV). 7. Should have rechargeable batteries (3.6 V). 8. Should have USB connectivity interface for PC and printer. 9. Should be supplied with autoinjector pen and disposable lancets.
2.2	**User's interface**	Manual
2.3	**Software and/ or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		

3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Noise-free system
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE		
4.1	**Power requirements**	NA
4.2	**Battery operated**	Yes
4.3	**Protection**	NA
4.4	**Power consumption**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Hb Strips
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Capable of operating continuously in ambient temperature -10 to 60 deg and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	NA

8.2	**Requirements for sign-off**	Supplier to perform safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	01 year
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. Certificate of calibration and inspection,
10.2	**Other accompanying documents**	NA
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer and supplier to be provided;
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

83. PORTABLE HANDHELD GLUCOMETER		
Version no.:		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Glucose self-testing
GMDN code(s)		CT296
GENERAL		
1. USE		
1.1	**Clinical purpose**	It intended to be used together for testing, either at the point-of-care or in self-testing by a layperson, for the quantitative measurement of glucose and/or ketones in a whole blood clinical specimen.
1.2	**Clinical department/ward**	All
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1. Should be open system having compatibility with any make of available glucose strips in open market. 2. Should have LCD display screen and auto shut off feature when not in use. 3. Display of the sugar reading should be in mg/dl. 4. Should have reading range/linearity from 20 to 700 mg/dl. 5. Should have a maximum reading time of less than 10 seconds 3. Should be supplied with autoinjector pen and disposable lancets. 4 Should have the feature of automatic code detection of glucose strips. 5. Should have a minimum memory of 100 tests
2.2	**User's interface**	LCD
2.3	**Software and/or standard of communication**	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Handheld Device
3.2	**Weight (lbs, kg)**	Handheld Device
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Handheld Device
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	**Power Requirements**	Battery powered
4.2	**Battery operated**	3-volt lithium coin cell battery or 2 x (AAA) Alkaline Batteries
4.3	**Protection**	NA

4.4	**Power consumption**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables/reagents (open, closed system)**	Glucose strips (able to use capillary blood samples) with availability in local market
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity upto 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards in case of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements forsign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	User training should be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	01 Years
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	User, technical and maintenance manuals should be supplied along with machine diagrams
10.2	**Other accompanying documents**	NA
	11. NOTES	
11.1	**Other information**	Contact details of manufacturer and supplier should be provided.
11.2	**Recommendations or Warnings**	NA

84. Auditory Brainstem Response Machine (Brainstem Evoked Response Audiometer (BERA))		
Version no.:		01
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	**Clinical purpose**	BERA is an electro physiological test procedure which studies the electrical potential generated at the various levels of the auditory system starting from cochlea to cortex. The BERA (Brain stem Auditory Evoked Responses) test is performed by an audiologist in children to check for hearing loss.
1.2	**Used by clinical department/ward**	PMR Diagnostics
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• The system should be able to perform the BERA, ASSR. • Should have following test types: - AEP: Chirp, Click & tone burst ABR, ECochG, Cortical AEP: AMLR, LLR, & Electrical ABR for pre surgical & Post-surgical Cochlear Implant procedure, VEMP • Should have ability to record under physiological and electromagnetic noises. • Impedance measurement should be built in and displayed on screen. Should have facility of display multiple panels of waveforms simultaneously. Should have the facility of continuous live display of ongoing input signals. • Should have stimulus polarity: Condensation, Rarefaction, Alternating. Should have absolute or stimulus relative masking types (NBN & White noise). Should have two isolated channels. Should have digital Butterworth High pass/ Low pass Filter. • Signal presentation : right, left and both • Should have pre-programmed auto tests. Should have facility of unlimited number of user defined test protocols. • Stimulus types: CE- Chirp, Click, Pure Tone, Tone Burst, tone pip Transducer: Insert ear phones, Headphones and Bone Vibrator • Intensity: 0-130dB nHL • Tone Burst 10 to 130 dB on 250 to 8000 Hz • Analysis time should be short: -50 to 700 ms • Should be amplifier frequency response 0.2 to 10,000 Hz. • Should have repetition rates 0.2 to 100 depending on modality.

		Technical Specification for ASSR (Optional) • Stimulus - Modulated Tone, Clicks • Intensity: up to 125 dB SPL • Frequency response up to 5000Hz or better • Should be able to test multiple frequencies simultaneously for both ears. • Automatic Generation of Audiogram in SPL/ HL • Phasor diagram should be generated automatically. • Frequency and intensity-based phasor diagram. • FFT Values should be displayed. • Should have spectrum graph. **Technical Specification for VEMP** • It should be 2 channels. • Transducer type: Ear-Tone ABR insert phone with VEMP stimulus/Position indicator. • Stimuli: Click and Tone Bursts. • Should have automatic test protocols for Click and Tone burst. • Patient communication: Talk forward
2.2	**User's interface**	Digital Display
2.3	**Software and/ or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism
3.5	**Mobility, portability**	NA
4. ENERGY SOURCE		
4.1	**Power requirements**	220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	Suitable UPS with maintenance free batteries.
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by vendor.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional);** **Spare parts (main ones);** **Consumables/reagents (open, closed system)**	Should be supplied with following accessories: 1. Insert Earphone 01 no. 2. Electrodes 6mm cup 12 nos. 3. Electrodes 10 mm cup 12 nos. 4. Electrode linker 02 nos. 5. Skin preparation gel 01 no. 6. Conductive paste 01 no.

		7. Infant ear tips 3.5 mm 20 nos, 8. Infant ear tips 4.0mm 20 nos. 9. Foam ear tips, 10mm 100 nos. 10. Disposable Electrodes25 nos. 11. Foam ear tips, 13mm 100 nos. 12. User Manual 01 no. 13. Ear Hug/ Halo muffin 100 Nos. 14. Insert adaptor for ear hug/Halo muffin – 02 sets
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	As specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 4. Satisfactory certificate for any existing installation from government hospital.

10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

85. CELL COUNTER SEMI-AUTOMATIC (3 PART)		
Version no.:		02
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Haematological cell analyser IVD
GMDN code(s)		35476
GENERAL		
1. USE		
1.1	**Clinical purpose**	An automated laboratory instrument intended to be used for the enumeration of a haematological cell population, using technology to measure and calculate white cell, redcell and platelet parameters and indices in a clinical specimen.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• The system should have End point, kinetic, fixed time and turbidimetric mode. • The system should be capable of 3 part WBC differential, estimating minimum 18 parameters with linearity (WBC, TC, RBC, Hb, hematocrit, MCV, MCH, MCHc, RDW- SD/RDW-CV, PLT, MPV, Pt Crit, PDW, PLCR optional). • The system should have memory of minimum10000 patient samples. • The system should have high intensity LED sourcefor Hb estimation. • The system should have dual mode – flow cell and cuvette. Non-cyanide based is preferable. • External keyboard. • Automated standby and wake up. • Auto probe cleaning and sample dilution preferable. • System must have throughput of at least 60 samples per hour. • QC Mode: LJ, SD, CV, QC histogram • Provision for Bar Code/QR code reading should be available • Built-in voltage stabilizer and test results printing facility. • The equipment should have in-built digital display unit and PC interface facility
2.2	**User's interface**	• Touch screen (Coloured) • Provision for bi-directional LIS/HIS interface shouldbe available.

2.3	**Software and/or standard of communication (wherever required)**	To be provided by manufacturer
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	N/A
3.2	**Weight (lbs, kg)**	N/A
3.4	**Noise (in dBA)**	N/A
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and theheat should be disbursed through a cooling mechanism.
3.6	**Mobility, portability**	Stationary laboratory Installation.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	**Power Requirements**	220 +-10% VAC, 50 HZ
4.2	**Battery operated**	UPS system with minimum 1 hour back up
4.7	**Protection**	Internal electrical protection
4.8	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional);Spare parts (main ones); Consumables/reagents(open, closed system)**	• 2D-Barcode/ QR code Scanner. • Built-in Thermal printer and provision for external printer. • All the consumables, controls and calibrators and any other reagents or items required for conducting 1000 tests should be mentioned and supplied with the equipment. • Online UPS for minimum 1 hour back up.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performanceand safety standards (specific to the device type);Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.

		5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	As specified by manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	• Supplier to perform installation, safety and operation checks before handover. • Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 3 years, including all spares and calibration. • Preventive maintenance visits atleast one in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, servicemanuals, other manuals**	Should provide 2 sets (hardcopy and soft copy) of: 1) User, technical and maintenance manuals to be supplied inEnglish/Hindi language along with machine diagrams. 2) List of equipment and procedures required for localcalibration and routine maintenance. 3) Service and operation manuals (original and copy) to beprovided. 4) Advanced maintenance tasks documentation. 5) Certificate of calibration and inspection;
10.2	**Other accompanying documents**	List of essential spare/ accessories, reagents/all other consumables along with their part number and cost shouldbe quoted
11. NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier, and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning signs would be adequately displayed;

86. ERYTHROCYTE SEDIMENTATION RATE (ESR) ANALYSER		
Version no.:		01
Date:		August 2023
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		Erythrocyte Sedimentation rate (ESR) analyser IVD
GMDN Code		56691
GENERAL		
1. USE		
1.1	Clinical Purpose	An electrically powered automated laboratory instrument intended to be used to determine the erythrocyte sedimentation rate (ESR) of red blood cells in an anticoagulated whole blood specimen.
1.2	Used by clinical department/ward	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical Characteristics (Specific to this type of device)	• The instrument should carry out automated ESR analysis directly from closed ESR tubes or EDTA vacutainers using the principle of sedimentation of red blood cells (Westergren Method). • Should be able to load minimum 10 samples at a time. Both batch and continuous. • Measuring range in mm: 1-140 using optical sensor. • Throughput should be at least 60 samples/hr. • ESR controls should have long shelf life (minimum 6 months). • Should have an inbuilt Bar code Reader and printer. • Should have auto mixing facility as per ICSH & CLSI requirements. • Have provision for internal temperature correction at 18°C or 37° C • Should have feature of haemocrit HCT correction • Should offer random access testing • Data storage capacity: upto 1000 test results. • Internal Quality Control Management with minimum two level of controls should be provided. • Should have facility for calibration and should comply with National/International quality standards • Provision for bi-directional LIS interface should be available. • Provision for Bar Code/QR code reading should be available.
		• The equipment should have in-built digital display unit and PC interface facility.

2.2	**User's Interface**	Microcontroller based LCD/LED Display Unit
2.3	**Software and/or standard of communication (Wherever required)**	All software installations or updates should be done free of cost during warranty period.
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (in mm)	NA
3.2	Weight	NA
3.3	Noise	NA
3.5	Heat Dissipation	NA
3.6	Mobility/Portability	Stationary Lab Installation
4. ENERGY SOURCE		
4.1	Power input	220VAC +/- 10%, 50 Hz.
4.2	Battery Operated	Yes
4.3	Protection	Internal Electrical Safety
4.2	Power consumption	As per Manufacturer/Supplier specified
5. ACCESSORIES, SPARE PARTS AND CONSUMABLES		
5.1	Accessories, (mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (Open, closed system)	1. Reagents and consumables to carry out minimum 200 tests 2. One additional set of RS 232 cables 3. Other Standard accessories.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere /Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer.
7. STANDARDS & SAFETY		

7.1	Certificates (pre-market, sanitary, ..);Performance and safety standards (specific to the device type);Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	Training of staff (medical, paramedical, technicians)	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	**1.** 3 years, including all spares and calibration. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of all the important spares and accessories, with their part numbers and cost needs to be submitted.
11. NOTES		

11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of Vendor and local service agent needs to be provided.
11.2	Recommendations or warnings	Any specific recommendation or warning to be followed for ensuring optimal and safe utilization of medical device needs to be mentioned.

87. SEMI-AUTOMATED BIOCHEMISTRY ANALYSER		
Version no.:		02
Date:		August 2023
Done by: (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Multichannel clinical chemistry analyzer IVD, laboratory
GMDN code		56677
GENERAL		
1. USE		
1.1	**Clinical purpose**	A semi-automated laboratory instrument intended to be usedfor the qualitative and quantitative in vitro determination of multiple clinical chemistry analytes in a clinical specimen. Analytes detected may include electrolytes, specific proteins, lipids and kidney, liver and cardiac function test analytes.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Analyzer should have ability to use external cuvettesand integrated flow cell. • Analyzer should have more than 200 programmablechannels. • Open Ended system preferably. • Analyzer should have 5 assay types: End point, Fixed time, Kinetic, absorbance and 1-point calibration with option for extended keyboard. • Analyzer should have calibration types: Linear factor, multi-point, point to point and Log-Log out • Facility for kinetic assay measurement with multiplestandard mode. • Should have minimum 10,000 Patient Result memory Storage • Should have light source with working life of more than 10000 hrs. • Should have complete visual range. • 3 levels control with day-to-day Levey Jenningschart stored and displayed. • Provision for Bar Code/QR code reading should beavailable. • The equipment should have in-built digital displayunit and PC interface facility
2.2	**User's interface**	• Facility for integration with PC • Provision for bi-directional LIS/HIS interface shouldbe available.
2.3	**Software and/or standardof communication**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions**	NA

	(metric)	
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and theheat should be disbursed through a cooling mechanism
3.5	**Mobility, portability**	Stationary lab Installation
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)	
4.1	**Power Requirements**	220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	UPS system for backup of minimum one hour
4.4	**Protection**	NA
4.5	**Power consumption**	To be specified by manufacturer/supplier
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional);Spare parts (main ones); Consumables/reagents(open, closed system)**	1. Light source/Lamp-1 no. 2. Micro pipettes (5 No.) - 2 variable (5-50), (100-1000) 3. Tips 500 - small and 500- big.
	BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type);Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature,**	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.

	values, quality, tolerance	
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operationchecks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. 2. Preventive maintenance visits at least one in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hardcopy and soft-copy) of: - 1) User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams. 2) List of equipment and procedures required for local calibration and routine maintenance. 3) Service and operation manuals (original and copy) to be provided. 4) Advanced maintenance tasks documentation. 5) Certificate of calibration and inspection
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbersand cost.
11. NOTES		
11.1	**Service Support Contactdetails (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent tobe provided.
11.2	**Recommendations orwarnings**	Any warning signs would be adequately displayed

88. ELISA READER AND WASHER		
Version no.:		01
Date:		August 2023
Done by: (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		-
GMDN code		-
GENERAL		
1. USE		
1.1	**Clinical purpose**	A laboratory technique that uses antibodies linked to enzymes to detect and measure the amount of a substancein a solution, such as serum. The assay uses a solid-phasetype of enzyme immunoassay to detect the presence of a ligand in a liquid sample using antibodies directed against the protein to be measured.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• The device should be fully automated and easy to operate with 8 and 12 channel manifold. • It should be capable to wash flat, round and V bottom plates and strips. • It should have large display along with more than40-50 program storage facility. • System should have calibration facility. • System should have warning/alarm for full waste container and empty wash bottle. • Residual volume after washing should be < 2ul. • It should have specially designed peristaltic pump to dispense 50 - 400 µl. • It should be supplied with waste container, wash bottle and rinse bottle of capacity 2 liters withtubings. • It should have option of programming wash cycleswith capacity for storing at least 50 wash protocols. • Cross wise aspiration, overflow washing and bottom washing. • Bichromatic/Optics with six standard wavelengths for ELISA kits. • Trichromatic Light source. • Internal Printer with port for external printer. • Should read ELISA Plate Horizontally A to H and vertically 1 to 12. • Photometric Accuracy should be ±3%. • Should have a resolution of 0.001 Abs. • Print out of whole plate in Matrix Format. • Linear measurement range 0 to 4 Absorbance unit.

		• 8 filter wheel capacity with Interference. • Filters of 405, 450, 492, 620 nm with at least 4 extra positions within the range of 400-750 nm.
2.2	**User Interface**	Compatibility with external Printer
2.3	**Software and/or standard of communication (wherever required)**	NA
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.6	**Mobility, portability**	Stationary lab Installation.
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)	
4.1	**Power Requirements**	220VAC +/- 10%, 50 Hz
4.2	**Battery operated**	Online UPS with minimum one hour back up
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by vendor
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional); Spareparts(main ones); Consumables/ reagents (open, closed system)**	1) Paper rolls for printer- 10 nos. 2) Online UPS for minimum one hour back up
	BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
	7. STANDARDS AND SAFETY	

7.1	**Certificates (pre-market, sanitary, ...); Performance andsafety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. 2. Preventive maintenance visits atleast one in eachquarter
10. DOCUMENTATION		
10.1	**Operating manuals, servicemanuals, other manuals**	Should provide 2 sets (hardcopy and soft copy) of: 1) User, technical and maintenance manuals to be supplied inEnglish/Hindi language along with machine diagrams. 2) Service and operation manuals (original and copy) to beprovided. 3) Certificate of calibration and inspection;
10.2	**Other accompanying documents**	List of essential spare/ accessories, reagents/all other consumables along with their part number and cost should be quoted.
11. NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent tobe provided;
11.2	**Recommendations or warnings**	Any warning signs should be adequately displayed.

89. GLYCATED HAEMOGLOBIN (HBA1C) ANALYSER		
Version no.:		01
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		Glycated haemoglobin (HbA1C) analyzer IVD
GMDN code(s)		35968
GENERAL		
1. USE		
1.1	**Clinical purpose**	A laboratory instrument intended to be used for the quantitative measurement of glycated haemoglobin(HbA1c), also known as glycolhaemoglobin, glycosylated haemoglobin or glucosylated haemoglobin, in a clinical specimen.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type ofdevice)**	• Automated integrated system for HbA1c testing. (HPLC based preferably) • Should have LED light source of wavelength (400-800) nm • Should have automatic mixing by using motor, if required. • Should have automatic calibration system. • Should provide NGSP/IFCC certificate for equipment at the time of installation. • System should have a throughput of 40 test/hour. • Measuring range: HbA1c 3-20%. • High precision, CV ≤5% • Should have inbuilt battery backup • The system should have provision of bi-directional data flow. • The equipment should have digital display unitand PC interface facility. • The system should be equipped with an automated barcode/QR code reading facility
2.2	**User's interface**	Digital Display
2.3	**Software and/ or standard of communication (wherever required**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA

3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	220VAC +/- 10%, 50 Hz
4.2	**Battery operated**	Should have inbuilt battery backup
4.3	**Protection**	Internal electrical safety
4.4	**Power consumption**	To be specified by vendor.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard,optional); Spare parts (main ones); Consumables/reagents(open, closed system)**	Should provide Sample rack – 1 No, Pipette rack – 1 No, Printer rolls – 2 Nos, necessary pipettes and any other additional accessories required to perform the HbA1C test.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience(air conditioning, humidity, dust …)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterilityissues**	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary); Performance and safety standards (specific to the devicetype); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality,tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented

9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. 2. Preventive maintenance visits at least one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) tobe provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier, and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

90. CHEMILUMINESCENT IMMUNOASSAY ANALYSER IVD		
Version no.:		01
Date:		August 2023
Done by: (Name/institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		Chemiluminescent immunoassay analyzer IVD
GMDNS code(s)		56701
GENERAL		
1. USE		
1.1	**Clinical purpose**	An automated laboratory instrument intended to be usedfor the qualitative and quantitative in vitro determination of chemical and biological markers (e.g., protein, drug, hormone, microbial toxin) in a clinical specimen.
1.2	**Used by clinical departme nt/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type ofdevice)**	• Fully Automated multi-channel analyzer based on chemiluminescence technology. • The instrument should provide comprehensive process check that performs, monitors, and verifies each step throughput sample and assay processing. • Continuous loading capacity of 30 or more samples. • Throughput of atleast 60 test per hour or more • The system should be able to read multiple barcode types or QR code. • It should have capability to do the assay in continuous, random, batch & stat mode. • Serum, plasma, urine, whole blood (assay-dependent) type of samples handling system. • System to use latest mixing probe technology to mix the samples and reagents to have complete uniformity with clot detection facility. • It should have the facility for bubble detection, check viscosity, sample level and short samples to ensure accuracy preventing erroneous results due to improper samples. • It should have an ability to do on board dilution andreflex dilution for high and abnormal samples. • It should have facility for automated probe cleaning or disposable tips system to avoid reagent carryover. • Should have onboard liquid waste container (4 litre), direct drain optional. • Should be a microprocessor-controlled device withdigital display.

		• 2-point re-calibration facility, switched mode power supply, automated instrument calibration, user friendly and intelligent software • System should have software that automatically generates LJ charts for QC and have appropriate alerts. • Provision for Bar Code/QR code reading should be available. • The equipment should have in-built digital display unit and PC interface facility. • External USB storage available
2.2	**User's interface**	• Digital display • Provision for bi-directional LIS/HIS interface should be available.
2.3	**Software and/ or standard of communication (Wherever required)**	Built - in/Automatic/compatible, windows based with data processing management system with complete back up of data base for calibration, control, patient sample results on daily basis.
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	System should have on-board cooling facility to maintain the temperature of the reagents.
3.5	**Mobility, portability**	Stationary lab Installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	**Power Supply:** 220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	Online UPS with minimum one hour back up
4.3	**Protection**	Internal electrical protection.
4.4	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	• External Printer to take printout of patient results andQC reports. • Online UPS with minimum one hour backup
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience(air conditioning, humidity, dust …)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.

6.2	**User's care, Cleaning, Disinfection & Sterilityissues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre- market, sanitary,); Performance and safety standards (specific to the devicetype); Local and/or International**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality,tolerance**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operationchecks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. 2. Preventive maintenance visits atleast one in eachquarter
10. DOCUMENTATION		
10.1	**Operating manuals,set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should besupplied in English/Hindi language along with machine diagrams. 2. Advanced maintenance tasks documentation. 3. Certificate of calibration and inspection, 4. Satisfactory certificate for any existing installationfrom government hospital.
10.2	**Other accompanying Documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		

11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and localservice agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

91. BLOOD CULTURE ANALYSER IVD		
Version no.:		01
Date:		August 2023
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		Blood culture analyzer IVD
GMDN Code		56739
GENERAL		
1. USE		
1.1	Clinical Purpose	An electrically powered automated laboratoryinstrument intended to be used for the qualitative and/orquantitative in vitro determination of microorganism growth in a blood culture preparation or other clinical specimen, with or without subsequent identification of the organism.
1.2	Used by clinical department/ward	Clinical Diagnostic Laboratory
TECHNICAL		
2. Technical Characteristics		
2.1	Technical Characteristics(Specific to this type of device)	• Fully automated modular system capable of culturing blood, sterile body fluids for bacteriaand fungi. • Capacity: Minimum 25 bottle positions. • System should have optimized recovery of organism with continuous agitation. • System should be based on sensitive fluorescence/colorimetric technology for interpretation of results. • The system should be modular with the possibility of expansion on requirement. • The culture media must have strong resin based antibiotic removal devices to minimize chances of false negatives due to high antibiotics in specimens. • The system should be capable of processing both adult and pediatric samples. • QC should be based on test parameters. • Provision for bi-directional LIS interface should be available. • The system should have sample accession facilityusing bar code/ QR code reader. • Should have PC interface facility.
2.2	Software and/or standard of communication (wherever required)	Within the warranty period needs to cover free of cost upgradation and re-installation
3. PHYSICAL CHARACTERISTIC		

3.1	Dimensions (in mm)	NA
3.2	Weight	NA
3.3	Noise	NA
3.4	Heat Dissipation	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	Mobility/Portability	Stationary Lab Installation
4. ENERGY SOURCE		
4.1	Power input	220VAC +/- 10%, 50 Hz.
4.2	Power consumption	To be specified by manufacturer.
5. ACCESSORIES, SPARE PARTS AND CONSUMABLE		
5.1	Accessories, (mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system)	The system should be supplied in a complete system with all accessories, hardware's like computer, printer etcand the required software.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere /Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuouslyin ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	As indicated by Manufacturer
7. STANDARDS & SAFETY		
7.1	Certificates (pre-market, sanitary); Performance and safety standards (specific to the device type); Local and/orinternational	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards in case of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, Tolerance	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		

9.1	Warranty	• 03 years • Preventive Maintenance visits at least once in each quarter
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Certificate of calibration and inspection,
10.2	Other accompanyingdocuments	List of all the important spares and accessories, with their part numbers and cost needs to be submitted.
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of Vendor and local service agent needs to be provided
11.2	Recommendations orwarnings	Any specific recommendation or warning to be followed for ensuring optimal and safe utilization of medicaldevice needs to be mentioned.

92. DENTAL X-RAY		
Version no. :		02
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Radiographic Units, Dental, Extra oral
UMDNS code(s)		18427
GENERAL		
1. USE		
1.1	Clinical purpose	Dental radiographic units in which the dental film is placed inan external film cassette. These units are designed for imaging the maxillofacial region using a rotating x-ray beam (panoramic radiography), which produces a single image of the dental arch as a fixed elliptical shape; and/or to obtain images of the complete skull (cephalometric radiography) or of a region of interest from various angles. Some extra oral units can produce multilayered transverse images of the maxillary and mandibular jaws (cross-sectional tomography).
1.2	Used by clinical department/ward	Dental Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. It should be digital. 2. Suitable for Adult and Pediatrics. 3. Minimum total filtration shall be 2.5 mm Al. 4. Heat capacity shall be ≥20,000 HU. 5. Focal spot size should be 0.6 mm. 6. Constant potential; high-frequency required. 7. Automatic Exposure Control (AEC) is required which is used to control the length of x-ray exposure. The exposure timer controls the length of the x-ray exposure; typical exposure times are 0.1 to 5 seconds for cephalometric radiography and 5 to 20 seconds for panoramic radiography. Patient selection Switches (Thin, Normal and Obese) 8. Feather touch keypad and length of exposure cable should be5 to 6 meters. 9. Ease of operation as all the functions can be selected from the remote control as well as timer. 10. An excellent output of 60 kV to 80 kV, 0 mAs to 15 mAs. 11. Exposure time shall be ≤ 15 sec 12. Audible and Visual indication of “X-Ray On” (Radiation indications). 13. Should provide compatible voltage stabilizer (Built in/External). 14. Source to Image Distance(SID) 400-500 mm 15. Magnification : 1.2-1.5x
2.2	User's interface	Manual

2.3	Software and/or standard of communication(where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise-free system
3.4	Heat dissipation	Should maintain nominal temp and the heat should be disbursed through a cooling mechanism
3.5	Mobility, portability	Stationary Installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	220 +/- 10% VAC, 50 Hz
4.2	Battery operated	No
4.3	Protection	High voltage protection for X-ray tube.
4.4	Power consumption	To be specified by vendor.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)	Machine should be provided with following items, 1. Two numbers of BARC approved whole body lead aprons with all attachments and thyroid color.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience(air conditioning, humidity, dust …)	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterilityissues	To be specified by manufacturer
7. STANDARDS AND SAFETY		

7.1	Certificates (pre-market, sanitary,..); Performanceand safety standards (specific to the device type); Local and/or international	1. Should be CDSCO and AERB approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: (nature,values, quality)	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	Requirements for sign-off	Supplier to perform safety and operation check before hand over.
8.3	Training of staff (medical, paramedical, technicians)	Training of users on operation and basic maintenance.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Advanced maintenance tasks documentation. 4. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	Service Support Contactdetails (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent tobe provided.
11.2	Recommendations orwarnings	Any warning sign would be adequately displayed.

93. ELECTROPHORESIS ANALYZER		
Version no.:		02
Date:		August 2023
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		Electrophoresis analyzer IVD
GMDN Code		57837
GENERAL		
1. USE		
1.1	Clinical Purpose	An electrically-powered automated laboratory instrumentor system intended to be used for the qualitative and quantitative in vitro determination of various molecules (e.g., DNA, RNA, proteins) in a clinical specimen based on their size, ionic charge and/or rate of migration through an electrically charged field.
1.2	Used by clinical department/ward	Clinical Diagnostic Laboratory
TECHNICAL		
2. Technical Characteristics		
2.1	Technical Characteristics(Specific to this type of device)	• Should be able to undertake multiparametric analysis like serum, protein, isoenzymes, immunofixation. • Automated sample application and sequential processing of each step of electrophoresis with disposable applicators • Gel imaging, interpretation and reporting software should be available with the system • The system should use deuterium lamp with optical fibers for emission and reception. • The system needs to have in built tube mixer. • Should have provision for automatic recycling of Buffer and Stainer. • System should have in built reading capacity. • Should be capable of automatically arrange the loading of all the reagents, standardizing furtherthe electrophoretical process. • The instrument should be capable of quality control measures • The through put of the system should be, at least i. Hemoglobin – 8 samples/ hour ii. Protein – 20 samples/ hour • Automatically able to manage the reagents and automatic washing cycle before the switch-off ofthe unit. • Provision for bi-directional LIS interface should be available.
2.2	Software and/or standardof communication	NA

	(wherever required)	
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (in mm)	NA
3.2	Weight	NA
3.3	Noise	NA
3.4	Heat Dissipation	NA
3.5	Mobility/Portability	NA
4. ENERGY SOURCE		
4.1	Power input	220VAC +/- 10%, 50 Hz.
4.2	Battery Operated	Online UPS system with minimum one hour back up.
4.3	Protection	Internal electrical safety
4.2	Power consumption	As per Manufacturer/Supplier specified
5. ACCESSORIES, SPARE PARTS AND CONSUMABLES		
5.1	Accessories, (mandatory,Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system)	1. To be supplied with computer (minimum i5 processor,500 GB HDD and 4 GB RAM), A4 size laser printer and appropriate bar code reader 2. Start-up kit for at least 200 tests should be provided. 3. Online UPS system with minimum one hour back up
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere /Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterilityissues	As indicated by Manufacturer
7. STANDARDS & SAFETY		
7.1	Certificates (pre-market, sanitary, ..);Performanceand safety standards (specific to the device type);Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality,	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.

	tolerance	
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	Training of staff (medical,paramedical, technicians)	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	1. 3 years, including all spares and calibration. 2. Preventive maintenance visits atleast one in eachquarter.
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, othermanuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Certificate of calibration and inspection, 4. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost.
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of Vendor and local service agent needsto be provided
11.2	Recommendations or warnings	Any specific recommendation or warning to be followed for ensuring optimal and safe utilization of medical device needs to be mentioned.

94. BP APPARATUS (ANEROID)		
Version no. :		02
Date:		August 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Sphygmomanometers
GMDN code(s)		
GENERAL		
1. USE		
1.1	**Clinical purpose**	Measures blood pressure non-invasively by displaying the pressure in a cuff wrapped around a patient's arm. The systolic and diastolic pressure is usually assessed by listening to Korotk off sounds generated by arterial blood flow using a stethoscope simultaneously.
1.2	**Used by clinical department/ward**	All clinical departments
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1) Should be based on non-mercurial aneroid based measurement technology . 2) Should be able to measure blood pressure in adult as well as pediatric patients. 3) Should have a dial type display, with a hook which can be attached to the blood pressure cuff. 4) Pressure measurement range should be 0 to 300 mm Hg systolic and 40 to 200mm Hg diastolic. 5) Pressure measurement accuracy of +/- 3 to 5mm Hg 6) Manual inflation of blood pressure cuff.
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA), heat dissipation**	NA
3.4	**Mobility, portability**	Yes
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.4	**Power consumption**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory,**	Adult arm cuffs of size medium & large and pediatric size, inflation bulb, tubing.

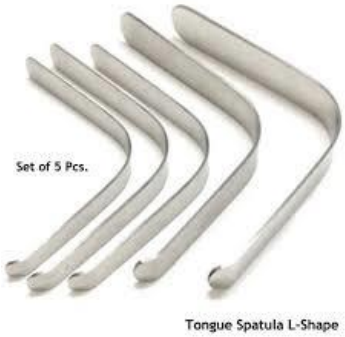
	standard, optional) **Spare parts (main ones)** **Consumables / reagents(open, closed system)**	Dial mano meter.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance(air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterilityissues**	NA
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ...); Performanceand safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over.
8.3	**Training of staff (medical,paramedical, technicians)**	NA
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1 years
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, othermanuals**	User manuals to be supplied in English languagealong with machine diagrams.
10.2	**Other accompanying documents**	NA
11. NOTES		
11.1	**Service Support Contactdetails (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations orwarnings**	NA

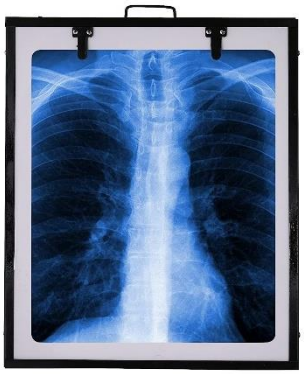
95. BP Apparatus/Sphygmomanometer (Digital)		
Version no. :		02
Date:		August 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Automatic-inflation electronic sphygmomanometer, portable, arm/wrist
GMDN code(s)		45617
GENERAL		
1. USE		
1.1	**Clinical purpose**	Digital Sphygmomanometers are automated, providing blood pressure reading without needing someone to operate the cuff or listen to blood flow sounds
1.2	**Used by clinical department/ward**	All clinical departments
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1) Should be able to measure blood pressure and pulse rate in adult patients. 2) Should be based on oscillometric measurement technology, using dynamic linear deflation method. 3) Should have backlit digital display with easy to view readings in dim light. 4) Pressure measurement range should be 60 to 250 mm Hg systolic, and 40 to 200mm Hg diastolic. 5) Pressure display accuracy of +/- 2 to 3 mm Hg 6) Pulse rate measurement range of 40 to 220 per minute 7) Pulse measurement accuracy of within +/- 5% 8) Single button operation for start and stop functions with auto-inflation of blood pressure cuff. 9) The device should have rechargeable battery.
2.2	**User's interface**	Digital Display
2.3	**Software and/or standard of communication (where ever required)**	In-built
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	YES
4.3	**Protection**	NA

4.4	**Power consumption**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional)**	Adult arm cuffs of size small, medium, large & extra-large and inflation bulb, tubing • Battery Charger
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Easy to clean
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ...); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	01 Year
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams.
10.2	**Other accompanying documents**	NA
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	Contact details of manufacturer and supplier to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

MISCELLANEOUS EQUIPMENT

Sl. No.	Title	Specifications	Image of the equipment
96.	Foetoscope	• Description: Used to listen to the heart rate of a foetus during pregnancy by placing the scope over the abdomen. • Material: Standard hollow horn, should be made up of rust proof metal, with smooth lips for tight contact with the skin. • Should be at least 8 inches long.	
97.	Punctum Dilator	• Description: A surgical device with cylindrical corrugated metal handle with conical pointed tips on both sides that ophthalmic surgeons use to broaden obstructed tear ducts, looking towards to restore the tear flow and discharge the lachrymal system. • Material: Made up of premium stainless steel; polished finish for aesthetic and corrosion resistance, and autoclavable.	
98.	Tuning fork	• Description: An acoustic resonator in the form of a two-pronged fork with the prongs (tines) formed from a U-shaped bar of premium quality elastic metal • Material: Alloy of steel, nickel and chromium, called Elinvar • Frequency: 128, 256, 512 Hz, each fork is individually tested to match the specific frequency. • ISO 13485/BIS/CE Certificate	
99.	Goinometer	• Description Measuring tool used in occupational therapy and physical therapy to measure a joint's axis and range of motion. • Material: made up of Stainless steel, two 180-degree scale in opposite direction, measures about 50mm x 200 length	

		• Should have ISO certification for quality standards.	
100.	Percussion Hammer/Reflex Hammer	• Description: Used to examine the reflexes of the deep muscle tender and to check the abnormalities, if any, of the nervous system. • Material: Should be made of stainless-steel arm with a rubber head (triangular in shape) for percussion. • Length: 7.5" (Approx.) with a comfortable handle grip. • Should have ISO 13485/BIS/CE/ISI/ISO:9001	
101.	Head Lamp	• Description: Light weight, wearable head lamp using LED technology to produce intense white light for spot examination and illumination. • Adjustable leather head band. Ion lithium rechargeable battery. • Minimum 3.5 - 4 hours of continuous operating time. • Features: Pure white light of high intensity. Light spot focalization system with multidirectional adjustment of the light.	
102.	Tongue depressor	• Description: L-Shaped tongue Spatula used to depress the tongue to allow for examination of the mouth and throat • Material: made of rustproof premium quality Stainless Steel • Length: 5 to 6 inches approx. with varying sizes for pediatric and adult use. • Packed in set of 5 pcs, re-usable and autoclavable.	

103.	X-Ray View Box	• For viewing single X-ray films having dimensions of 15 x 5"x 25" (Lx D x H) with 2 nos. of 20W fluorescent tubes of 2 feet length each with necessary fittings in MS housing of 20 SWG and is duly powder coated. • View box to be fitted with white acrylic sheet to reduce glare and provide uniform illumination. • Grip clips/ grip rollers are to be provided to hold the film. • Drip tray for wet films	
104.	Ear and Nasal Suction/Aspirator	• The ear syringe used for cleaning the ear canal and nasal aspirator is used to clear the nasal passages of infants, children, and adults. • Should be made up of high-quality medical grade material. • Nasal aspirator consists of a soft, flexible tube with a bulb or chamber at one end and a nozzle at the other.	
105.	Proctoscope	• Description: Proctoscope is a short rigid single-use plastic or chromium plated metal (reusable) instrument with hollow interior and a tapering probe fitted with a handle and is used for visual examination of the lower part of rectum and anal canal • Diameter: Approx. 20-30 mm • Material: rust resistance, latex free material, autoclavable (for reusable)	
106.	Finger Exerciser web	• Description: used for hand strengthening and hand therapy. Excellent for physical therapy, conditioning, and rehabilitation. • Use to perform finger flexion, extension, opposition, and supination exercises • Material: latex-free material with high quality rubber with special agents added for durability and strength which can accommodate all hand sizes and strength levels • Dimension: 14" in diameter • Available in 6 resistance levels.	

107.	Walking Aid for training/Reciprocal walker	• Description: Lightweight foldable frame walker fitted with soft hand grip, used to provide stability. • Portability: foldable for easy storage and transportation • Material/Quality: made up of stainless steel rugged tubular frame to bear weight. • Distance between handgrips should be approx. 34 cms • Height: should be at least 175 cm, from ground and preferably adjustable/lockable. • Should have latex free handgrip with forearm support	
108.	Spirometer	• Description: Spirometer is used for lung exercises. • Should be compact, lightweight and made up of high-quality break-resistant plastic. • Should have 3 chambers for different inhalation rates consisting of 3-balls spirometer.