To Whomsoever it may concern

Please be advised that MoHFW has issued a guidelines regarding requirement/ non-requirement of USFDA/CE Certification etc. in procurement of medical devices vide their letter no. X.11035/379/2015/DFQCl dt 20th Feb 2018. (Copy Attached)

And as per the guidelines the following will be applicable:

"All the hospitals /Health institutions under Department of Health and Family Welfare are requested to ensure that in all cases of procurement of Medical Devices/medical equipment, the following shall be complied with:

(I) Medical Devices/ Equipment where Indian Standards are available:
Where Indian Standards are available, these would be sufficient and the indenting organisation shall not insist on any specification or standards like US FDA or CE Certifications etc.

(II) Medical Devices/ Equipment where Indian Standards are not available:
In order to ensure quality of the devices /equipment being purchased, the indenting organisation would be free to lay down the standards of ISO/US FDA Or CE Certification, in such cases."

Thus as all the specification drafted by NHSRC will adhere to the above guidelines and as such the requirement of USFDA/CE will be replaced by the following:

"The equipment should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards like BIS/CDSO/AERB is not available.)"

This is for information of all concerned

[Signature]
Advisor, Healthcare Technology
OFFICE MEMORANDUM

Subject: Guidelines regarding requirement/non-requirement of USFDA/CE certification, etc. in procurement of medical devices-Reg.

The undersigned is directed to refer to the D.O letter No. X.11035/379/2015-DFQC dated 18.07.2016 issued to the authorities as per the list attached (copy enclosed), written by Shri K B Agarwal, former Additional Secretary, Department of Health & Family Welfare on the subject mentioned above.

2. All the Hospitals/Health Institutes/Organizations under Department of Health & Family Welfare are requested to ensure that in all cases of procurement of medical devices/medical equipment, the following shall be compiled with:

(I) **Medical devices/equipment where Indian standards are available:**

Wherever the Indian standards are available, these would be sufficient and the indenting organization shall not insist on any specification or standards like USFDA or CE certification etc.

(ii) **Medical devices/equipment where Indian standards are not available:**

In order to ensure quality of the devices/equipment being purchased, the indenting organization would be free to lay down the standards of ISO or USFDA or CE certification, in such cases.

Encl: A/a.

(D.N Sahoo)
Deputy Secretary to the Govt. of India
Telefax: 23061656

To
All heads of Health Institutes/organizations/Hospitals under Department of Health & Family Welfare.

Copy to:
All JS of this Ministry.