F.No.NEIGR/S&P/M-04/2016-17

OFFICE MEMORANDUM

Dated: 16/03/2018

- Reference OM No.X.11035/379/2015-DFQC(Pt), dated 20/02/2018, pertaining to guidelines related to certification of medical devices/medical equipment.
- In all cases of procurement of medical devices/medical equipment, the following is to be complied with:

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

Whenever 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.

*Signature*

Deputy Director (Admin), NEIGRIHMS
Tel: 0364-2538010

Copy for information to:

1. P.A. to Director/ S&PO/ MS/ Dean/ Principal (Medical College)/ Principal (College of Nursing)/ BME.
2. All Head /In charge of Departments, NEIGRIHMS, Shillong
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 complied 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.