पूर्वोत्तर इंदिरा गांधी क्षेत्रीय स्वास्थ्य एवं आयुर्विज्ञान संस्थान, शिलांग
NORTH EASTERN INDIRA GANDHI REGIONAL INSTITUTE OF HEALTH & MEDICAL SCIENCES, SHILLONG
(भारत सरकार, स्वास्थ्य एवं परिवार कल्याण मंत्रालय, स्वायत संस्थान)
(An Autonomous Institute, Ministry of Health and Family Welfare, Government of India)
निदेशक ब्लॉक, मावडीयांगडीयांग, शिलांग - 793018 मेघालय
Director's Block, Mawdiangdiang, Shillong - 793018 Meghalaya

E-mail - info.neigrihms@nic.in
www.neigrihms.nic.in
EPABX : (0364) 2538176/8061

F.No.NEIGR/S&P/M-04/2016-17 Dated: 16/03/2018
21/3/2018

OFFICE MEMORANDUM

- 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.

21/3/18

D. T. Umdor
Deputy Director (Admn), 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

No.X.11035/379/2015-DFQC (Pt)
Government of India
Ministry of Health & Family Welfare
Department of Health & Family Welfare
(Drugs Regulation Section)

Nirman Bhavan, New Delhi
Dated the 20 Feb., 2018

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.

17
14/3/18