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

F.No. NEIGR/S&P/A-03/2016-17/Pt

Date: 13/04/2021

OFFICE MEMORANDUM

Subject: Guidelines regarding requirement of certification in procurement of medical devices – Reg.

Reference Office Memorandum F.No.X.11035/374/2019-DRS dated: 9th March 2021, from Government of India, Ministry of Health and Family Welfare, Drugs Regulation Section, regarding requirement of certification in procurement of medical devices.(Copy of OM is enclosed).

Also, the Ministry's OM No. X.11035/379/2015-DFQC(Pt) dated 20.02.2018 (copy of OM is enclosed) in supersession of the instructions contained therein, the guidelines regarding requirement of certification in procurement of medical devices have been modified and the same is under:

a) The medical device shall conform to the standards laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 1985 (63 of 1985) or as may be notified by the Ministry of Health and Family Welfare, Government of India, from time to time.
b) Where no relevant standard of any medical device has been laid down as specified under (a) above, such device shall conform to the standard laid down by the International Organisation for Standardization (ISO) or the International Electro Technical Commission (IEC), or by any other pharmacopoeial standards.
c) In case no standards have been specified under (a) and (b) above, the device shall conform to the validated manufacturer's standards.

All the Departments under the Institute are requested to ensure that in all cases of procurement of medical devices/medical equipment, the above guidelines shall be complied with.

(D. T. Umdor)
Deputy Director (Admn.)
NEIGRIHMS

Copy for information and necessary action to:

1. P.A. to DDA/MS/Dean NEIGRIHMS, Shillong.
2. The Deputy Financial Adviser, NEIGRIHMS, Shillong/ DMS (General/Medical/Surgical)
3. All Head/In-charge of Departments, NEIGRIHMS, Shillong/ Bio Medical Engineer
4. Executive Engineer (E)/© /Estate Officer (C).
5. Store & Procurement Officer, NEIGRIHMS, Shillong.
6. Principal, College of Nursing, NEIGRIHMS, Shillong.
7. Sr. Account Officer/ Accounts Officer/ Assistant Accounts Officer, NEIGRIHMS, Shillong.
8. Librarian, NEIGRIHMS, Shillong
9. The AR Estt-I & III, AO GAD, Estt-II, NEIGRIHMS, Shillong
10. I/C Central/ Medical/ Ancillary Stores/ Sanitary Officer/In-Charge Laundry/Mr Wello Warjri, Mr.'s Amanda Syiem, NEIGRIHMS, Shillong for perusal and record.
11. DPA for uploading on the Institute's website.

Mr Romanus ~ for immediate website upload / Dr 10/4/25
Depts / All Store & pharmacy professionals

F.No. X.11035/374/2019-DRS
Government of India
Ministry of Health and Family Welfare
(Department of Health & Family Welfare)
Drugs Regulation Section
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Nirman Bhawan, New Delhi
Dated 9th March, 2021

OFFICE MEMORANDUM

Subject: Guidelines regarding requirement of certification in procurement of medical devices- Regarding

The undersigned is directed to refer to this Ministry's OM No. X.11035/379/2015- DFQC (Pt) dated 20.02.2018 and to say that, in supersession of the instructions contained therein, the guidelines regarding requirement of certification in procurement of medical devices have been modified and the same would be as under:

a) the medical device shall conform to the standards laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 1985 (63 of 1985) or as may be notified by the Ministry of Health and Family Welfare, Government of India, from time to time.

b) where no relevant standard of any medical device has been laid down as specified under (a) above, such device shall conform to the standard laid down by the International Organisation for Standardization (ISO) or the International Electro Technical Commission (IEC), or by any other pharmacopoeial standards.

c) in case no standards have been specified under (a) and (b) above, the device shall conform to the validated manufacturer's standards.

2. All the Hospitals/Health Institutes/Organizations under Department of Health and Family Welfare are requested to ensure that in all cases of procurement of medical devices/ medical equipment, the above guidelines shall be complied with.

Encl: A/a

(Bikash R Mahato)
Under Secretary to the Govt. of India
Tele: 23061141

To
All Heads of Health Institutes/Organisations / Hospitals under Department of Health & Family Welfare

Copy to:
All Joint Secretaries in this Ministry

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.

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14/3/18