

ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI-110029.
STORE SECTION (DO)

No.F. 35-01/2017/SO(DO)/AIIMS (vol.2)

Dated:-

Sub.:- Guidelines regarding requirement of certification in procurement of medical devices - regarding.

The undersigned is directed to circulate a File No. X.11035/374/2019-DRS dated 09.03.2021(E-mail dated 10.03.2021) on the subject noted above received from dated 15.03.2021 Mr. Bikash R Mahato, Under Secretary to the Govt. of India, Ministry of Health & Family Welfare, Department MOHFW Section to all concerned with the request to strictly guidance and compliance with the above order.



Sr. Store Officer (DO)

Encl.:- As above

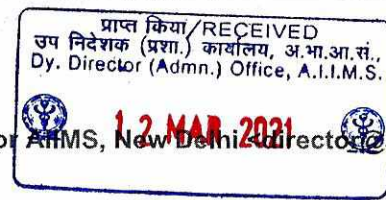
DISTRIBUTION:-

1. **Prof-In-Charge Computer Facility:** - with request to upload the same on AIIMS website. And also send through email to all AIIMS Chief/ HoD Deptt./M.S./Store Section (Content Provider).

Mr. Aman

Ms. Anukita Singh
01/04/21.

Mr. Aman
03/04/21.



Director A.I.M.S., New Delhi, Director@aiims.edu>

Guidelines regarding requirement of Certification in procurement of Medical Devices-Regarding

1 message

DrugsRegulationSec. <drugsdiv-mohfw@gov.in>

Wed, Mar 10, 2021 at 3:51 PM

To: director aiims <director.aiims@gmail.com>, 123dks@gmail.com, Director JIPMER <director@jipmer.edu.in>, agupta786@gmail.com, admin@aiimsraipur.edu.in, director@aiimsraipur.edu.in, PGIMER CHANDIGARH <pgimer-chd@nic.in>, dpgichd@hotmail.com, Jagat Ram <dpgi@pgimer.edu.in>, aiihph@cal.vsnl.net.in, mishralok@gmail.com, dram cip <dram_cip@rediffmail.com>, director@aiishmysore.in, Director Office NIMHANS <dirstaff@nimhans.ac.in>, msofficesjh@gmail.com, MEDICAL SUPERINTENDENT <msoffice@vmmc-sjh.nic.in>, med sup rmlh <med.sup.rmlh@gmail.com>, ROHITSARIN DIRECTOR <r.sarin@nitrd.nic.in>, director@rims.edu.in, directorlhmc@gmail.com, N N Mathur Director <director-lhmc@gov.in>, admin@vpci.org.in, sngaur@gmail.com, admin@aiimspatna.org, director@aiimspatna.org, skdeuri1959@gmail.com, dean@mgims.ac.in, director <director@aiims.edu>, director <director@aiimsbhopal.edu.in>, director <director@aiimsbhubaneswar.edu.in>, director <director@aiimsjodhpur.edu.in>, director <director@aiismangalagiri.edu.in>, director <director@shriraminstitute.org>, "Director, CSIR-IGIB" <director@igib.res.in>, director@aiims.ac.in, dda@aiimsraipur.edu.in, info@aiimsrishikesh.edu.in Cc: Ms Gayatri Mishra <g.mishra@nic.in>, Nipun Vinayak <js.me-mohfw@nic.in>, Mr Lav Agarwal <alav@ias.nic.in>, Mr Sunil Sharma <sunil.sharma62@gov.in>, Mr Vishal Chauhan <vishal.chauhan@ias.nic.in>, Ms Rekha Shukla <rekha.shukla@nic.in>, Mr Vikas Sheel <sheelv@nic.in>, Nipun Vinayak <vinayaknipun@nic.in>, vinayaknipun <vinayaknipun@gov.in>, Ms Preeti Pant <p.preeti@nic.in>, Vandana Jain <vandana.jain@nic.in>, Mrs Padmaja Singh <padmaja.singh@nic.in>, "Dr(Mr) Dr Mandeep Kumar Bhandari" <mandeep@ias.nic.in>, RAJIV WADHAWAN <r.wadhawan15@gov.in>, "Bikash R. Mahato" <bikash.mahato@nic.in>

Sir/Madam,

Please find attached OM no X.11035/374/2019-DRS dated 09th March 2021 on Guidelines regarding requirement of Certification in procurement of Medical Devices.

From: "Drug Regulation Section" <drugsdiv-mohfw@gov.in>

To: "director aiims" <director.aiims@gmail.com>, 123dks@gmail.com, director@jipmer.edu.in, agupta786@gmail.com, admin@aiimsraipur.edu.in, director@aiimsraipur.edu.in, pgimer-chd@nic.in, dpgichd@hotmail.com, dpgi@pgimer.edu.in, aiihph@cal.vsnl.net.in, mishralok@gmail.com, "dram cip" <dram_cip@rediffmail.com>, director@aiishmysore.in, dirstaff@nimhans.ac.in, msofficesjh@gmail.com, msoffice@vmmc-sjh.nic.in, "med sup rmlh" <med.sup.rmlh@gmail.com>, "r sarin" <r.sarin@nitrd.nic.in>, director@rims.edu.in, directorlhmc@gmail.com, director-lhmc@gov.in, admin@vpci.org.in, sngaur@gmail.com, director@aiimsbhubaneswar.edu.in, director@aiimsbhopal.edu.in, director@aiimsjodhpur.edu.in, admin@aiimspatna.org, director@aiimspatna.org, skdeuri1959@gmail.com, dean@mgims.ac.in, msofficesjh@gmail.com, "SubhashChandra Parija" <director@jipmer.edu.in>

Cc: "DN Sahoo" <Sahoo.dn@nic.in>

Sent: Wednesday, February 21, 2018 2:11:13 PM

Subject: 1 of 3,022 Guidelines regarding requirement/no-requirement of USFDA/CE Certification etc., in procurement of medical devices

Sir/Madam,

Please find the attachment on the subject cited above for necessary action.

With Warm Regards:

Drug Regulation Section,
D/o Health and Family Welfare,
Ministry of Health and Family Welfare,
Nirman Bhawan, New Delhi.

Pl. endorse to all stores & with
request to comply.

We may endorse copies to all Dean(R),
Chiefs/ Med. Supt & all HOD

Dr S (DO)

SNR
13/3/2021

DDA

12/3

Guidelines regarding requirement of Certification in procurement.pdf
1102K

Dr Stores Officer (I)
13/3/2021
HCC (Procure.)

F.No. X.11035/374/2019-DRS
Government of India
Ministry of Health and Family Welfare
(Department of Health & Family Welfare)

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:

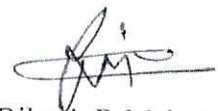
a) the medical device shall conform to the standards laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 1985 (63 of 1985) or as may be notified by the Ministry of Health and Family Welfare, Government of India, from time to time.

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

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:

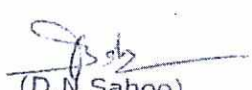
(i) **Medical devices/equipment where Indian standards are available:**

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.

✓ S P O

ES
14/3/18

