F. No. 23/104/2022-HSMD
Government of India
Ministry of Environment, Forest and Climate Change
(HSM Division)

Jal Block, 2nd Floor,
Indira Paryavaran Bhawan,
Jor Bagh Road, Aliganj,
New Delhi - 110003

Dated: 15th October, 2024

OFFICE MEMORANDUM

Subject: Revised List of High End and High Value used/refurbished Medical Equipment other than critical care medical equipment- reg.

In super session of the Ministry's OM of even No. dated 19th June, 2023 and in reference to the Directorate General of Health Services (DGHS), Ministry of Health & Family Welfare (MoHFW) OM dated 20th August, 2024 forwarding therewith revised list of High End and High Value used/refurbished Medical Equipment, the revised list of High End and High Value used/refurbished Medical Equipment other than critical care medical equipment is as follows:

S. No.	Name of Equipment
1.	MRI
2.	CT
3.	PET-CT
4.	SPECT/SPECT-CT/Gamma Camera
5.	Mammography
6.	Interventional Radiology Equipment
7.	Radiotherapy Devices
8.	OT Integration System
9.	4K Advance Laparoscopy Surgery System
10.	Molecular Diagnostic – Molecular infectious disease diagnostics system
11.	Microbiology – advanced mass spectrometry microbial identification system
12.	Robotic Assisted Surgical System, Instruments and Accessories
13.	Femtosecond ophthalmic solid – state laser system
14.	Phacoemulsification and vitrectomy system
15.	Ophthalmic Excimer Laser system
16.	OCT posterior and anterior segment
17.	Fundus imaging system preferably ultrawide field along with FFA and ICG
18.	Corneal topography
19.	Optical Bio meter
20.	High end operating microscope
21.	Ablation system
22.	Endoscopic Camera system
23.	Endoscopes

24.	Orthopaedic Robotic Navigation System
25.	High End Medical – grade monitors
26.	Image Management System
27.	Medical –grade electromechanical drill
28.	Flow control pump
29.	Insufflation device
30.	NCV/EMG system
31.	EEG system
32.	Repetitive transcranial magnatic stimulator
33.	Video Urodynamic system with Chair
34.	Cryo Ablation system
35.	High Intensity Focused Ultrasound System
36.	3D – 4K Laparoscopy System
37.	High End Dental Chair
38.	Cone-Beam Computed Tomography Systems (CBCT)

2. The revised list of High End and High Value used Medical Equipment other than critical care medical equipment will be in force from the date of issue of this OM. Other Conditions for obtaining import permission of used/refurbished High End High value medical equipment as prescribed by the Technical Review Committee (TRC)/ Expert Committee (EC) constituted in the Ministry in its earlier meeting, shall remain the same and are attached at **Annexure 'I'**.

3. This issues with the approval of the Competent Authority.

(Ved Prakash Mishra)
Director

To,

1. **The Joint Secretary,**
   Department of Health & Family Welfare,
   Ministry of Health & Family Welfare,
   Nirman Bhawan, New Delhi - 110001.

2. **The Deputy Director General,**
   Directorate General Health Services,
   Department of Health & Family Welfare,
   Ministry of Health & Family Welfare,
   Nirman Bhawan, New Delhi - 110001.

3. **The Director General,**
   Directorate General of Foreign Trade,
   Udyog Bhawan, H-Wing, Gate No.2,
   Maulana Azad Road, New Delhi - 110011.

4. **The Director (Customs),**
   Ministry of Finance,
   Department of Revenue, Central Board of Excise and Customs,
   North Block, New Delhi - 110 001.

Annexure 'I'

Import of used/refurbished High End High value medical equipment

a. Conditions/Pre-requisites for Import of used/refurbished High End High value medical equipment:

- Form 5 of Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 as amended from time to time.
- The equipment must be enlisted in Ministry's O.M. dated 19th June, 2023, as advised by DGHS.
- Justification for import.
- The High End High Value Used/refurbished Medical Devices having residual life of minimum 07 years, duly certified by a Chartered Engineer or a certificate from any accredited agency of exporting country indicating the functionality, manufacturing date, residual life and serial number, shall be allowed for import for reuse purpose.
- If being imported on returnable basis than undertaking for re-export, then specifying the time period.
- Details of previous import if there has been any and confirmation regarding their re-export.
- In case of capital items particularly medical equipment the fact that the machine has been refurbished at the OEM factory and after sales service is provided by the supplier/ importer.
- Acknowledgment for receipt of copy of import application from concerned State Pollution Control Board (SPCB)/ Pollution Control Committee (PCC).
- Certification from exporting company for accepting the re-export of defective or second hand EEEs, after the specified time.
- Document depicting the status of employment generation indicating the no. of people benefited.
- Extended Producer Responsibility - registration as producer if the EEEs to be imported are listed in Schedule-I of the E-Waste (Management) Rules, 2022 as amended from time to time.
- Copy of the previous latest permission issued by this Ministry, if any.
- Undertaking declaring that such equipment has not been phased out from the importing country and is not considered obsolete in that country.
- Undertaking declaring that such equipment does not contain any hazardous material/ substances listed under any international regulation/ law and or by government of India.
- OEM/Indian subsidiary of that equipment shall ensure the availability of hardware and software support including spare parts/consumables for the period of warranty and comprehensive maintenance contract (CMC).
- Equipment should have minimum warranty period of one year, followed by three years of CMC.
- OEM/Indian subsidiary must give in writing about the availability of spare parts/consumables.
- The equipment shall be disposed after the end of life as per the prevailing Hazardous and Other Wastes (Management & Transboundary Movement) Rules, 2016 as amended from time to time and E-Waste (Management) Rules, 2022 as amended from time to time.
- The importer has to obtain an import authorization from DGFT, wherever the import policy of such items is restricted under ITC(HS)/Foreign Trade Policy/Procedures and any other statutory NOC/clearances as applicable.

- The Customs Authority at the Air Cargos/Ports/ICDs shall verify the documents prior to clearing the consignments. They can also take action as per the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 as amended from time to time and the Customs Act, 1962 against importers found to be violating the norms.

b. In case import application is made by third party on behalf of actual user, List/Mapping of End Users for each equipment must be provided and confirmed purchase order from end user should be available.

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