

Instruction No. 08/2024-Customs

F.No.401/40/2021-Cus.III
Government of India
Ministry of Finance, Department of Revenue
(Central Board of Indirect Taxes & Customs)

Room No.229A, North Block,
New Delhi, Dated, 05.04.2024

To

All Principal Chief Commissioners/ Chief Commissioners of Customs/ Customs
(Preventive) /Customs and Central Taxes
All Principal Commissioners/ Commissioners Customs/ Customs (Preventive)
All Principal Director Generals/Director Generals under CBIC

Subject: - : Exemption for import of High End and High Value used Medical Equipment other than critical care medical equipment Hazardous and Other under Wastes (Management and Transboundary Movement) Second Amendment Rules, 2022 dated 23rd December, 2022- reg

Madam/Sir,

Reference is invited to Ministry of Environment, Forest and Climate Change (MOEFCC) (HSM Division) OM dated 15.12.2023 enclosing OM dt. 19.06.2023, 19.05.2023 and 06.07.2023 (copies attached.) and Hazardous and Other Wastes (Management and Transboundary Movement) Second Amendment Rules, 2022 on 23rd December, 2022

2. Vide above OM, MOEFCC has stated that Hazardous and Other Wastes (Management and Transboundary Movement) Second Amendment Rules, 2022 dated 23rd December, 2022 where notified wherein High End and High Value Used Medical Equipment other than Used Critical Care Medical Equipment is included in Part 'B' of Schedule III of Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 (HOWM Rules, 2016) and are allowed to be imported by actual user or by Original Equipment Manufacturers (OEM) or Indian Subsidiary of OEM or Trader on behalf of actual user for reuse. Further, it has been informed that as this item falls under Schedule III Part 'B' of HOWM Rules, 2016, hence import of above referred equipment is restricted and cannot be imported without permission from the MOEFCC, with conditions imposed in the permission.

3. In this regard, A list of 50 High End and High Value used/refurbished Medical Equipment other than critical care medical equipment have been provided vide MoEFCC OM dated 19.06.2023, which have been allowed to be imported as per above mentioned conditions.

4. It is to note that, Used Critical care medical equipment is covered under

Basel NO. B1110 of Schedule VI of the HOWM Rules, and is prohibited for import for re-use. For reference, MoEFCC vide their OM dated 19.05.2023 (copy attached) has provided a list of 14 critical care medical equipment as follows:

- i. High End Ventilators
- ii. Nitric Oxide Generator
- iii. Flexible Bronchoscope
- iv. ABG Machines
- v. Haemodialysis machines
- vi. Continuous Renal Replacement Therapy (CRRT)
- vii. CO,SVR, ScvO2 Monitor
- viii. Intubating video scope
- ix. ICU dedicated Ultrasound and Echo Machine
- x. Beside X-ray machine
- xi. Extra-Corporeal Membrane Oxygenator (ECMO)
- xii. IABP
- xiii. Percutaneous dilatation tracheostomy kit
- xiv. Defibrillator with transcutaneous pacemaker

5 . It is requested that necessary action may be taken to sensitize officers under your jurisdiction regarding the said matter. The difficulties, if any, may be brought to the notice of the Board.

Hindi version follows

Encls: as stated above.

Yours faithfully,



(R. Ananth)
Director (Customs)
Email: dircus@nic.in
Tele: 011 23093908

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

Date: 15th December, 2023

OFFICE MEMORANDUM

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

This is in continuation to this Ministry's OM of even number dated 19th June, 2023 providing therewith list of High End and High Value used/refurbished Medical Equipment other than critical care medical equipment, as suggested by DGHS, which can be imported. However, this import is subject to a number of conditions and is restricted. A representation has been received in this regard stating that above policy is not being followed strictly.

2. Hence, it is once again clarified that above referred High End and High Value Used Medical Equipment other than Used Critical Care Medical Equipment is allowed to be imported by actual user or by Original Equipment Manufacturers (OEM) or Indian Subsidiary of OEM or Trader on behalf of actual user for re-use. Further, this item falls under Schedule III Part 'B' of HOWM Rules, 2016, hence import of above referred equipments is restricted and cannot be imported without permission from the Ministry of Environment, Forest and Climate Change, with conditions imposed in the permission. The OMs dated 19th June, 2023 and 6th July, 2023 are enclosed for ready reference.

3. This OM is in supersession of earlier OMs and any permission given earlier (before 19th June, 2023) is not valid.


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

To,

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

2. **The Chairman**, Ministry of Finance, Department of Revenue, Central Board of Indirect Taxes and Customs, North Block, New Delhi - 110 001.

3. **The Joint Secretary (Customs)**, Ministry of Finance, Department of Revenue, Central Board of Indirect Taxes and Customs, North Block, New Delhi - 110 001. (to ensure the compliance please).


(Ved Prakash Mishra)
Director

Handwritten notes:
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Dr. (am) (SW)
The issue is
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01/11/23
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Dr. Deepan J
Ats (SW) PLS see
09-01-2024

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

Level II, Jal Block,
Indira Paryavaran Bhawan,
Jor Bagh Road, Ali Ganj,
New Delhi - 110003

Date: 6th July, 2023

Subject: Representation against permission to allow import of High End and High value used Medical Equipment other than critical care medical equipment - reg.

This has reference to e-mail dated 04.07.2023 received from Deputy Director General of Foreign Trade, Directorate General of Foreign Trade (DGFT), Department of Commerce (DoC), Ministry of Commerce forwarding the representation of M/s SS Innovations Pvt Ltd expressing concern regarding the import and use of refurbished/re-use medical equipment's, particularly Robotic Assisted Surgical System, Instruments and Accessories. Dy DGFT seek inputs/comments of MoEFCC on the same. Reference is also invited to several representations received in the Ministry regarding Ministry's notification dated 23rd December, 2022 allowing import of High End and High value used Medical Equipment other than critical care medical equipment for re-use purpose and OM dated 19th June, 2023 providing list of High End and High value used Medical Equipment other than critical care medical equipment.

2. In this regard, it is to inform you that Ministry were in receipt of various representations from FICCI, All India Pre-Owned Medical Equipment Supplier Association and Other Associations regarding import of Pre-owned/ Refurbished devices & Clarification regarding import of Critical Care Medical Equipment. Repeated request were also made to allow import of used medical equipment by third party so as to facilitate smaller healthcare facilities. These representations were referred to Technical Review Committee (TRC) constituted in the Ministry. TRC considering the prevailing status of medical facilities in the country and difficulties faced by small health care facilities in importing the costly high end devices and maintenance thereof, recommended the import of High End and High Value Used Medical Equipment other than Used Critical Care Medical Equipment by actual user or by Original Equipment Manufacturers (OEM) or Indian Subsidiary of OEM or Trader on behalf of actual user for re-use. This will not only facilitate smaller health care facilities in Tier-II/III cities but also provide affordable medical services to poor people.

TRC while recommending import of High End and High Value Used Medical Equipment other than Used Critical Care Medical Equipment inter-alia suggested that (i) Such equipment has not been phased out from the importing country and is not considered obsolete in that country; (ii) Such equipment does not contain any hazardous material/ substances listed under any international regulation/ law and or by government of India; (iii) The equipment must have a minimum residual life of 7 years (as specified by Chartered Engineer of exporting country) for which supplier or manufacturer must provide hardware and software support including warranty; (iv) The importer shall dispose the equipment after the end life as per the E-waste rules, 2016.

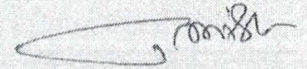
3. The above recommendation of TRC were accepted by the Ministry and accordingly, Ministry amended Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 and allow import of High End and High Value Used Medical Equipment other than Used Critical Care Medical Equipment.

4. Further, Directorate General of Health Services (DGHS), Ministry of Health & Family Welfare (MoHFW) vide OM dated 5th June, 2023 forwarded list of High End and High Value used Medical Equipment other than critical care medical equipment along with Terms and Conditions for import for reuse purpose which inter-alia includes that 'equipment manufactured in India should not be imported, as per 'Make in India' policy'. Thereafter, OM dated 19th June, 2023 was issued by the Ministry providing list of High End and High value used Medical Equipment.

5. In the light of above, it is to clarify that the suggestions given by TRC and DGHS, MoHFW will be taken into account while considering the application of import of High End and High value used Medical Equipment other than critical care medical equipment. The import permissions will be given by the Expert Committee of the Ministry with specified conditions and all the concerns raised in this regard will be duly considered, including 'make in India Policy; and Atm Nirbhar Bharat Policy of the Government.

This has approval of the competent authority.

Yours sincerely



(Ved Prakash Mishra)

Director

Email: mishra.vp@gov.in

Phone No.: 011-20819236

To,

Ministry of Commerce and Industry
(Kind Attn: **Shri Sanjay Kumar Tiwari**, Dy Director General of Foreign Trade)
Department of Commerce,
Directorate General of Foreign Trade,
Udyog Bhawan, New Delhi.
Email: sanjay.kt@nic.in

Copy to (through email):

1. The Managing Director, Accuster Technologies, Plot No. 424 CMR Building, Ghitorni, New Delhi - 110030.
2. The Director, Status Medical Equipments Pvt Ltd, M-9/A, Addl. MIDC, Satara, Maharashtra.
3. The Managing Director, Serwell Medi Equip (P) Ltd., 2, 1st floor, T.V. nagar, Ramapuram, Chennai.
4. The President, Prognosys Medical System Pvt Ltd., # 249, 4th Main Road, Chamarajpet, Bangalore - 560018.
5. The Managing Director, Xcellance Medical Technologies Pvt. Ltd., Shalya Avenue, W-239, MIDC, TTC Industrial Area, Navi Mumbai, Maharashtra.
6. The Director, Alan Electronics Systems Pvt. Ltd., F-75, MIDC Additional Ambarnath Industrial Area, Anand Nagar, Thane, Maharashtra.
7. Mitra Medical Services LLP, B-226, Okhla Industrial Area, Phase-1, New Delhi-110020.

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

Date: 19th June, 2023

OFFICE MEMORANDUM

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

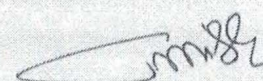
The undersigned is directed to refer to the Directorate General of Health Services (DGHS), Ministry of Health & Family Welfare (MoHFW) OM dated 5th June, 2023 forwarding therewith list of High End and High Value used Medical Equipment other than critical care medical equipment. The list of High End and High Value used 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.	High end X ray- Non -ICU
7.	Ultrasound – Non-ICU
8.	Interventional Radiology equipment
9.	C – arm (surgery)
10.	Radiotherapy Device
11.	Microbiology – Microbial identification & AST
12.	Microbiology – detecting systems for the presence or absence of microorganisms in Blood. Sterile body fluids.
13.	Multi parametric immunoassay Analyzer based on ELFA technology
14.	Molecular diagnostic – molecular infectious disease diagnostics systems
15.	Microbiology – advanced mass spectrometry microbial identification system
16.	Blood cell count analyzer
17.	Microscope slide maker / stainer
18.	Chemiluminescent immunoassay analyzer
19.	Clinical chemistry analyzer
20.	Immunohematology Auto Analyzer
21.	URINE Analyzers
22.	Robotic Assisted surgical system, instruments and Accessories
23.	Femtosecond ophthalmic solid – state laser system

24.	Phacoemulsification and vitrectomy system
25.	Ophthalmic Excimer Laser system
26.	OCT posterior and anterior segment
27.	Fundus imagine system preferably ultrawide field along with FFA and ICG
28.	Corneal topography
29.	Optical biometer
30.	Clinical corneal specular microscope
31.	High end operating microscope
32.	Ablation system
33.	Endoscopic Camera system
34.	Endoscopes
35.	Orthopedic Robotic Navigation system
36.	Medical – grade monitors
37.	Image Management system
38.	Medical –grade electromechanical drill
39.	Flow control pump
40.	Insufflation device
41.	NCV/EMG system
42.	EFG system
43.	Repetitive transcranial magnate stimulator
44.	Flexible video Ureterorenoscope with Monitor
45.	Video Urodynamic system with chair
46.	Cryo Ablation system
47.	4K Advance Laparoscopy surgery system
48.	OT integration system
49.	High intensity Focused Ultrasound system
50.	3D – 4K Laparoscopy system

2. Ministry of Environment, Forest and Climate Change has notified Hazardous and Other Wastes (Management and Transboundary Movement) Second Amendment Rules, 2022 on 23rd December, 2022 wherein High End and High Value Used Medical Equipment other than Used Critical Care Medical Equipment is included in Part 'B' of Schedule III of Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 and allowed to be imported by actual user or by Original Equipment Manufacturers (OEM) or Indian Subsidiary of OEM or Trader on behalf of actual user for re-use. It is also mentioned in the amended rules that "High End and High Value Medical Equipment is such medical equipment as specified by the MoHFW from time to time".

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.

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

Date: 19th May, 2023

OFFICE MEMORANDUM

Subject: List of Critical Care Medical Equipment - reg.

The undersigned is directed to refer to the Directorate General of Health Services (DGHS), Ministry of Health & Family Welfare (MoHFW) letter dated 13th October, 2022 (received in the Ministry through email dated 24th February, 2023) forwarding therewith updated lists of critical care medical equipment. The list of critical care medical equipment provided is as follows:

- i. High End Ventilators
- ii. Nitric Oxide Generator
- iii. Flexible Bronchoscope
- iv. ABG Machines
- v. Haemodialysis machines
- vi. Continuous Renal Replacement Therapy (CRRT)
- vii. CO, SVR, ScvO2 Monitor
- viii. Intubating video scope
- ix. ICU dedicated Ultrasound and Echo Machine
- x. Beside x-ray machine
- xi. Extra-Corporeal Membrane Oxygenator (ECMO)
- xii. IABP
- xiii. Percutaneous dilatation tracheostomy kit
- xiv. Defibrillator with transcutaneous pacemaker

2. Ministry of Environment, Forest and Climate Change (MoEFCC) has notified Hazardous and Other Wastes (Management and Transboundary Movement) (HOWM) Rules, 2016 and its amendments. The import/export of hazardous and other wastes is regulated through the said HOWM Rules, 2016. Used critical care medical equipment is covered under Basel No. B1110 of Schedule VI of the HOWM Rules, 2016, and is prohibited for import for re-use.

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.