

No.F.4/1/2021-PPD
Government of India
Ministry of Finance
Department of Expenditure
Procurement Policy Division
264-C, North Block, New Delhi.
6th January, 2022.

OFFICE MEMORANDUM

Subject: Relaxation on Global Tender Enquiry (GTE) under Rule 161(iv) of General Financial Rules (GFRs) 2017 for procurement of Medical Devices - reg.

Attention is invited to this Department's OM No. F.12/17/2019-PPD dated 15.05.2020 and 28.05.2020 regarding amendment in Rule 161(iv) of General Financial Rules (GFRs) 2017 stipulating that no Global Tender Enquiry (GTE) shall be invited for tenders upto Rs. 200 crore or such limit as may be prescribed by this Department from time to time. It further stipulates that in exceptional cases, where the Ministry or the Department feels that there are special reasons for GTE, it may record its detailed justification and seek prior approval for relaxation to the above Rule from the competent authority i.e. Secretary (Coordination), Cabinet Secretariat.

2. In this context, a reference has been received from Ministry of Health & Family Welfare (MoHFW) to exempt procuring entities from seeking approval for floating GTEs in respect of 128 Medical Devices etc. (list is enclosed as Annexure-A). It is stated by MoHFW that after due study of market conditions, there are no domestic manufacturers available for these 128 items.

3. The matter has been examined and it has been decided that 128 items listed at Annexure- A will be exempted from the instructions issued by this Department on 15.05.2020 and 28.05.2020 as above. This exemption will be valid for all the tenders issued for such items till 31.03.2023. MoHFW is requested to review domestic availability of these items at the end of 2022, keeping in view the Production Linked Incentive (PLI) scheme etc. launched by Department of Pharmaceuticals in Medical Devices and other relevant factors, in consultation with that Department.

4. This issues with the approval of Finance Secretary.

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06.01.2022*
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To

Secretaries of All Ministries/ Departments,

Copy to:

1. Secretary (Coordination), Cabinet Secretary.
2. Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, with respect to para 3.

Annexure- A

List of Medical Devices and IVDs, where local manufacturers are not available, as on 17.12.2021 (as verified with the Medical Devices Manufacturing Associations)

S.No.	Name of Medical Device/Equipment
1	Intra-aortic balloon Pump (IABP)
2	Video Assisted Thoracic Surgery (VATS) and Minimally Invasive Cardiac Surgery instrument set
3	Flow Track Cardiac Output Monitoring (EV1000)
4	Sander's Jet Ventilator for Emergency Airway
5	ENT Coblator system with standard set of wands
6	Automated Identification and antibiotic susceptibly system
7	Automated Semen Analyzer
8	Histopathology fully automated H& E slide Stainer
9	Fully Automated IHC Stainer
10	Auto PAP cervical cancer screening system with HPV
11	Automatic components preparation machine
12	Visual Field Analyzer
13	Cystoscope paediatric cystoscope
14	Flow Cytometer
15	Flexible cysto-nephoscopy
16	T Piece Resuscitator
17	CO2 Fraction Laser
18	Diode Laser
19	Q-Switched ND YAD Laser
20	Video Bronchoscope set Adult, Paediatric, and Neonatal
21	Surgical Operating Microscope
22	Cavitational /Cavitron - Ultrasonic Surgical Aspirator (CUSA)
23	Endobronchial Ultrasound System
24	Rotary Microtome
25	Magnifying surgical loupes
26	Endoscopic Saphenous Vein Harvesting (EVH) System
27	Intra operative Imaging and TTFM for CT Surgery
28	DEXA Scan
29	Radio surgery equipment
30	Near Infrared Spectroscopy
31	Fluid therapy
32	Near Infrared Spectrometer (NIRS)
33	Electro Physiology (EP) System
34	TOF Monitor/Watch for Neuro Muscular block

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35	Transcranial Doppler
36	Low Temperature Hydrogen Peroxide Gas Steriliser
37	Mannequins (Laerdal) for training of CPR for COVID Preparedness a) Intubation b) Cardio Pulmonary Resuscitation (CPR) c) Peripheral, Central and Arterial Cannulation d) Front of neck Access (Cricothyroidotomy and tracheostomy)
38	Image Analysis Tools/ Trinocular Compound Phase Contrast Microscope for Andrology Lab
39	Gas Analysis Apparatus Halden's Student Type
40	Gas Analyzer Automatic for CO ₂ , O ₂ and N ₂
41	High end Operating Microscope
42	Plasma Coblation System
43	Stroboscope
44	ENT Skull Base Navigation System
45	Automated Microbial Identification and Sensitivity System
46	NAT Analyzer
47	Cryostat
48	Vitek2-Automated Microbiology Susceptibility Testing Analyser
49	FFR Machine (Fractional Flow Reserve)
50	VIDAS
51	Kingfisher Flex
52	ACL Elite
53	Cytoprep Centrifuge with Vortex Mixer
54	Antigen Retrieval System
55	Trans Oesophageal Echo Cardiograph
56	IVUS -Volcano
57	STERRAD -100 NX All Clear
58	Minimally Invasive Cardiac Instruments
59	Impella
60	Endourology set
61	Cystoscope Karl Storz
62	Video Endoscopy Systems
63	Floppy wire with extra support 0 Coronary Angioplasty
64	Fully Automated Non-Contact Tonometer
65	Optical Biometer
66	Phaco Machine with Posterior and Anterior Vitrectomy
67	Portable Ultrasound Machine for Anaesthesia and Vascular Access
68	Activated Clotting Time Machine
69	Thromboelastogram (TEG)/ Thromboelastometer/ ROTEM
70	Bone Anchored Hearing Aid (BAHA) Sound Processor with Soft Band.

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71	CI Speech Processor for Cochlear Implant
72	Bi-Ventricular Pacemaker with Quadripolar LV Lead
73	DDD with Matching Electrodes Pacemaker
74	MRI Conditional Automatic Implantable Cardioverter Defibrillator (AICD)
75	MRI Conditional Cardiac Resynchronisation Therapy - Pacing (CRT- P)
76	Single Chamber (SSI) MRI Compatible Pacemaker
77	Single Chamber Temporary Pacemaker
78	Non-complain /semi complain /CTO coronary balloon.
79	Vacuum Heart Stabilizer System for off Pump CABG
80	Expandable Corpectomy device
81	Biomimetic Synthetic Absorbable Dural substitute of sizes
82	AO TRS Modular Drive for Drill/Reamer
83	AO TRS Modular Sagittal saw system
84	Battery Oscillator
85	Arthroscopy Systems
86	Navigation System for Neurosurgery & Orthopaedic Surgery
87	Time Lapse Embryo Imaging System
88	Portable Mobile Endoscopy Unit
89	Cryoprobe
90	Isothermal Calorimeter (ITC)
91	Electrical Impedance Tomography
92	FNIRS (Functional Near Infra-Red Spectroscopy) System
93	Automated Hand-Held Analyzer
94	Automated High Throughput Liquid Based Cytology (LBC) System
95	Automated IHC (Immuno Histochemistry Stainer)
96	Automated Slide Stainer for Histopathology
97	3T Digital PET/MR
98	Dual Particle Cyclotron on buyback basis
99	Sweat Collection and Chloride Estimation
100	Automated Bronchoscope Cleaning Equipment
101	Electronics and console for the existing 700 MHz NMR Spectrometer
102	Video bronchoscope with mobility of tip in four directions
103	Freeze Facture System
104	Cryo Plunge Freezing Unit
105	Biological High- Resolution Atomic Force Microscopy
106	Carbon Coater (Evaporator) for grids
107	Hemostasis Analyzer System
108	Auricular Reconstruction Set
109	Thin Layer Chromatography Liner Analyser for lipid analysis
110	Digital Slide Scanner System
111	Full Endoscopic lumbar IT & ED set

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112	Rapid Blood/Fluid Flow warmer
113	Fully Automated Computerized Archival System for Histopathology & Cytology Slides
114	Vacuum Assist Drainage Controller Device
115	VAP Care System
116	Cryoablation Unit
117	3D Printer Hardware with SLA (LFS) TM Technology and Machine interface software
118	Transcutaneous Oxygen Monitor
119	Non-Invasive Jugular Oximetry Monitor
120	Dedicated Solid-state cardiac SPECT Camera
121	Hemodynamic Recorded for Cardio Vascular Lab
122	Gel Documentation System
123	Automatic Colony Counter
124	Droplet Digital Polymerase Chain Reaction System (PCR)
125	Multi-block PCR Machine
126	Integrated Automated Charting System upgradable for ICU Monitoring System
127	Viscoelastic Global coagulation Testing Device
128	Robotic Surgery System with accessories