No.F.4/1/2023-PPD Government of India Ministry of Finance Department of Expenditure Procurement Policy Division

> 516, LokNayak Bhavan Khan Market, New Delhi, 17.02.2025

OFFICE MEMORANDUM

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

Reference: Department of Expenditure's OM No. F.4/1/2023-PPD (pt.) dated 28.06.2024.

Attention is invited to this Department's OM No. F.12/17/2019-PPD dated 15.05.2020 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. However, in exceptional cases, where the Ministry or the Department feels that there are special reasons for issuance of GTE, it may record its detailed justification and seek prior approval for relaxation to the above Rule from the competent authority.

2. In the above context, on the recommendation of Ministry of Health & Family Welfare (MoH&FW), 354 Medical Devices were exempted, vide above reference, from the instructions issued by this Department's OM Nos. 12/17/2019-PPD dated 15.05.2020 and 28.05.2020 till 31.03.2027 or till further orders.

3. This Department is now in receipt of OM No. Z-28015/35/2024-Proc-I(EPW) dated 30.09.2024 from MoH&FW suggesting changes in the nomenclature of certain medical devices. In view of the same, in supersession of earlier list, the list of 354 medical devices has now been revised (placed at Annexure-A), for which the said general relaxation under Rule 161(iv) of GFRs, 2017 will now be available till 31.03.2027 or till further orders.

4. This issues with the approval of Secretary (Expenditure).

Encls: As above.

(Sher Bahadur) Under Secretary (Procurement Policy) Tel.24653771 email: sher.bahadur@nic.in

To,

All the Secretaries and Financial Advisors to Government of India.

Copy to:

Secretary (Coordination), Cabinet Secretariat, Rashtrapati Bhawan, New Delhi.

Annexure-A

S.N.	GTE Device/Equipment
1	Continuous Plexus Block Management Catheter
2	Therapeutic Hypothermia Device
3	Integrated Difficult Airway Scope System
4	Digital Anaesthesia Machine with Digital Vaporisers, with Integrated Charting System
5	Apheresis Machine
6	Automated Blood Component Processor
7	Blood Component Irradiator
8	Dry Plasma Thawing System
9	Bio-Banking and Archiving Equipment
10	Electro Physiology System 2D/3D/EP catheters/instruments/accessories
11	Pacemakers (MRI Compatible/Leadless/DDDR)
12	Automatic Implantable Cardioverter Defibrillator (AICD)
13	Cardiac Resynchronisation Therapy-Pacing /Defibrillator (CRT-P/CRT-D)
14	Digital Subtraction Angiography System
15	Venous Coupler System
16	Paclitaxel Coated Balloon with Citrate Ester Excipient
17	Polymer Based Paclitaxel Eluting Stent for SFA
18	Pneumatic Hand Pump for Balloon Dilatation
19	Hydrophilic Coated Angiographic Catheter
20	3D Electro Anatomical Mapping System, with Consumables
21	Intra-Cardiac Echocardiography System, with Consumables
22	Suture Mediated Vessel Closure Device

S.N.	GTE Device/Equipment
23	Floppy Wire for Zero Coronary Angioplasty
24	Intra-operative Imaging and TTFM for Cardiothoracic Surgery
25	Intra Aortic Balloon Pump (IABP)
26	Haemostasis System for Cardiothoracic Surgery
27	Impella Device for Cardiothoracic Surgery
28	Hemodynamic Recorder for Cardio Vascular Lab
29	Cardiopulmonary Bypass Machine
30	Left Atrial Appendage Closure Device
31	Mitral Transcatheter Edge to Edge Repair Device
32	Valved Conduits for Heart Surgery
33	Bioprosthetic Heart Porcine Valve (Aortic/Mitral)
34	PDA Occluder (Double Disc)/ PVL/ LAA/ PFO/ ASD Occluder
35	Mitral Valve Annuloplasty Repair Ring
36	Self- Expanding Transcatheter Aortic Valve Implantation/Replacement Device
37	Pericardial Patches
38	High Frequency Chest Wall Oscillation Airway Clearance System
39	Endomotor (Endodontic Electric Motor)
40	Transillumination Caries Detector
41	Intraoral Scanner/ Image Plate Scanner
42	Orthopantomogram/CBCT Scan
43	Derma Scope/Dermatoscope
44	Intense Pulsed Light Therapy Device
45	Microneedling Radio Frequency Equipment

S.N.	GTE Device/Equipment
46	Microinjection System (Microinjector, Micromanipulator, Pipette Puller)
47	Motor Electric Dermabrader
48	Digital Stroboscope for ENT applications
49	Bone Anchored Hearing Aid (BAHA)
50	Cochlear Implant System (with or without Speech Processor)
51	Auricular Reconstruction Set
52	Endoscopic Sinus Surgery Set
53	ENT Workstation
54	OAE Screening System
55	Audiometer: Fixed/ Portable with or w/oTympanometer
56	Microdebrider for ENT Surgery
57	Sialendoscopy Set
58	High Resolution Manometry System
59	Wireless Capsule Endoscopy System
60	Fibro Scan Machine
61	Cholangioscopy Direct Visualization System with Accessories
62	Lumen Apposing Stents
63	High Definition Upper/Lower Flexible Endoscopic System for 3rd Space Endoscopy
64	Balloon Assisted Enteroscopy System
65	Reusable Flexible Dueodenoscope with Disposable Cap
66	Endoscopic Suturing and Plication Device for Bariatric Surgeries
67	Continuous Glucose Monitoring System
68	Platform Pedography System

S.N	. GTE Device/Equipment
69	Vaccum Assisted Breast Biopsy Machine
70	Mesh: Dual-layered/Preshaped/Absorbable
71	High Throughput Single Cell Analysis System
72	Automated Disintegration Test Apparatus
73	Dissolution Test Apparatus with Auto Sampler
74	Karl Fischer Titrator
75	Fourier Transform Infrared Spectroscopy
76	Bio-layer Interferometry
77	Flow Cytometry, Automated Cell Counter
78	Gas Analyzer Automatic for CO2, O2, N2
79	Cytoprep Centrifuge with Vortex Mixer
80	Activated Clotting Time Machine
81	Isothermal Calorimeter
82	Automated High Throughput Liquid Based Cytology (LBC) System
83	High Resolution Atomic Force Microscopy
84	Carbon Coater (Evaporator) for Grids
85	HighPerformanceChromatographyincludingThinLayer/HPLC/UHPLC/FPLC/HbHPLC/ HPLC (coupled with Mass Spectrometry)
86	Gel Imaging and Documentation System
87	Fully Automated NAT (Nucleic Acid Testing) System
88	Next Gen Sequencing Machine for DNA/RNA
89	Automated Cartridge Based Nucleic Acid Amplification System (CB-NAAT)
90	Polymerase Chain Reaction Machine (Multi-block/Gradient/Digital/Real Time)
91	Electrophoresis System: Agarose Gel/ Pulse Field/Vertical Gel/On-Chip

S.N.	GTE Device/Equipment
92	Automated Capillary DNA Sequencer
93	Automated Cell Viability Analyser with accessories
94	Automated Liquid Handling System for Serial Dilutions
95	Automated Nucleic Acid/ Protein Purification System
96	Automated Tissue Microarray & TMA Software
97	Cell Morphology Biosensor
98	Digital Slide Scanning System with Research Grade Microscope/Image Analysis Software
99	Electron Microscope
100	ELISA/ELISPOT Reader
101	Film Array Mulltiplex PCR System
102	Advanced Gas Chromatography equipment
103	Gel Electrophoresis Equipment with Accessories
104	High Content Screening Systems
105	Mass Spectrometers (including combinations with Liquid/Gas Chromatography)
106	Inductively Coupled Plasma Mass Spectrometry (ICP-MS)
107	Fluorescent Microscope/ Portable Fluorescent Microscope
108	Liquid Based Cytology System
109	Magnetic Bead Based Multiplex Immunoassay System
110	Ion Exchange Chromatography System
111	Automated Mercury Analyser
112	Bilirubin Analyser: Micro Method/ Transcutaneous
113	Metaphase Finder System with Fluorescence
114	Multimode Microplate Reader and Fluorimeter

S.N.	GTE Device/Equipment
115	Microwave Digestion System
116	Multiplex Protein Array/ Suspension Array System
117	Advanced Spectrophotometer
118	Point of Care Device for Cardiac Biomarkers (CKMB, Troponin, BNP, Myoglobin)
119	Ultracentrifuge Machines
120	Spectrometer/ Spectroscope/ Spectrofluorometer/ Texture Analyzer
121	Vacuum Assisted Automatic Tissue Processor
122	Western Blotting Apparatus
123	X-Ray Diffraction Equipment
124	Fully Automated Immunoassay Systems:EnzymeLinkedFluoroscentAssay(ELFA)/ChemiluminescenceEnzymeImmunoassay(CLEIA)/Electrochemiluminescence Immunoassay (ECLIA)
125	Fully Automated Clinical Chemistry Analyzer with integrated Electrochemiluminescence Immunoassay Analyzer (ECLIA) or other Immunoassay Systems
126	Thalassaemia and Hemoglobinopathy Testing System
127	Fully Automated High Throughput Hematology Analyzer, with Instruments and Accessories
128	Automated Sample Preparation System for Flow Cytometery
129	Fully Automated Nephelometry Analyzer
130	Microarray Facilities for Genetic Analysis
131	Fully Automated Slide Stainer: Histopathology/ Histochemistry/ Hematology
132	Workstation for Multi-PTM Analysis (Proteomics)
133	Automated Microbial Identification and Antibiotic Susceptibility System
134	Automatic Colony Counter
135	Automated Continuous Monitoring Blood Culture System
136	Automated Coverslipper

S.N.	GTE Device/Equipment
137	Automated T.B. Culture and Drug Sensitivity Detection System
138	Image Analyser cum Viral Foci Counter
139	Computerized Archival System for Histopathology & Cytology
140	Handheld ICG Fluorescence Imaging System
141	Video Assisted Thoracic Surgery (VATS) Set/Instruments
142	Cardiac Output Monitoring System
143	Slander's Jet Ventilator for Emergency Airway
144	T-Piece Resuscitator
145	CO2 Fraction Laser
146	Cavitational/Cavitron Ultrasonic Surgical Aspirator (CUSA)
147	Endoscopic Saphenous Vein Harvesting (EVH) System
148	Neuro Muscular Block Monitoring System
149	Trinocular Compound Phase Contrast Microscope (with Camera, Imaging system)
150	High End Operating Microscope
151	Cryostat/Cryomicrotone
152	FFR (Fractional Flow Reserve) Machine
153	Trans-Oesophageal Echo Cardiograph
154	Intravascular Ultrasound (IVUS)
155	Advanced Material Surgical Instruments-All Surgical Specialities
156	Thromboelastogram (TEG)/ Thromboelastometer (ROTEM)
157	TRS Modular Drive for Drill/Reamer/Sagittal Saw System
158	Mobile Endoscopy Unit
159	Electrical Impedance Tomography (EIT)

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S.N.	GTE Device/Equipment
160	FNIRS (Functional Near Infrared Spectroscopy) System
161	Video Bronchoscope with tip mobility in four directions
162	Freeze Fracture System
163	Cryo Plunge Freezing Unit
164	Full Endoscopic Lumbar IT & ED set
165	Rapid Blood /Fluid Flow Warmer
166	3D Printer Hardware and Machine Interface Software
167	Surgical Navigation System
168	Transcutaneous Oxygen Monitor
169	Non-Invasive Jugular Oximetry Monitor
170	Automated, Integrated ICU Monitoring and Charting System
171	Viscoelastic Global Coagulation Testing Device
172	Stimulator Systems: Transcranial/ Deep Brain/ Intra-operative
173	Cell Saver for Intra-operative Blood Salvage
174	CHNS (Carbon, Hydrogen, Nitrogen, Sulphur, Oxygen) Analyzer
175	Ultrasonic Cutting, Coagulation, Vessel Sealing System standalone or integrated with Bipolar Device, with Hand Instruments for Open/Laparoscopic Surgery
176	Radiofrequency Cutting, Coagulation and Vessel Sealing System standalone or integrated with Bipolar Device, with Hand Instruments for Open/Laproscopic Surgery
177	Cone Beam Computed Tomography: Mobile/Fixed/Intraoperative
178	Continuous Renal Replacement Therapy Machine
179	High Fidelity Mannequins for medical/surgical training
180	High Fidelity Simulator Systems: All Specialities
181	Extra Corporeal Shockwave Lithotripter
182	Atherectomy System: Coronary/Rotational/Orbital/Carotid

S.N.	GTE Device/Equipment
183	Fenestrated Stabilization System
184	Fibreoptic Bronchoscope for Adult/ Paediatric use
185	Hyperthermic Intravesical Chemotherapy (HIVEC) System
186	Intra Cranial Pressure Monitoring Device
187	Intraoperative Neuromonitoring System
188	Lymphovascular Microscope
189	MRI 3Tesla/Intraoperative MRI System
190	High End Intraoperative Ultrasound for Surgeries
191	High End Surgical Drill System with Attachments
192	Rigid Bronchoscope/ Rigid Esophagoscope (Adult/ Paediatric)
193	Super-microsurgery Systems
194	Endoscopic Ultrasound/ Endobronchial Ultrasound System (EUS/EBUS)
195	Endoscopic Ultrasound Fine Needle Biopsy (EBUS/EU/FNB) Machine with Needles
196	Cutting/Scoring Balloon: Peripheral/ Coronary
197	Pharmacomechanical Thrombectomy System
198	Peripheral Microcatheters (Coaxial, Braided)
199	Radio Frequency Ablation System
200	Cryoablation System, with Needles and Accessories
201	Cryoprobes, with Accessories
202	Drug Coated Beads Device for Chemoembolization
203	Transarterial Radioembolization Particles Device
204	Peripheral Coils: Micro/ Detachable
205	Embolic Protection System

S.N.	GTE Device/Equipment
206	Peripheral Support Catheter
207	Braided Self-Expandable Stents: Arterial/Venous/ Carotid
208	ICU Ventilator with Integrated Metabolic Monitoring/ Automatic Closed Loop Weaning with PAV (proportional assist ventillation)
209	Flexible Fibreoptic Cystoscope/ Uretero-Renoscope/ Cysto-Nephroscope/ Rhinolaryngoscope/ Bronchoscope/ Endoscope (Adult/Paediatric)
210	Flexible Video Cystoscope/ Uretroscope/Laryngoscope/Bronchoscope/Endoscope (3D, 4K)
211	Semiflexible Pleuro Videoscope System with Tissue Differentiation Technology
212	Uretero-Renoscope (Adult/Paediatric)
213	Cystoscope-Resectoscope (Adult/Paediatric)
214	Laproscopic Surgery Set with High-Definition Camera (3D/4K), (Adult/Paediatric) with Accessories
215	Laproscopic Surgery Set with Hysteroscope/Resectoscope (with Integrated Sheath), with Accessories
216	Robotic Surgical System for Soft Tissue/Cranium/Spine/Joint Replacement Surgeries
217	Occlusion Balloon Catheter: Temporary/ Micro (with variable diameters)
218	Braided Flexible Carotid/ Renal/Peripheral Guiding Sheath with Detachable Valve
219	ECMO (Extended Respiratory Support Application) Oxygenator (Adult/Peadiatric)
220	Homogenous Sized Embolization Microspheres
221	Advanced Perfusion System
222	Blood Parameters Monitoring System
223	Intelligent Powered Stapler and Reload
224	Selectable Staple Height Linear Cutter
225	Circular Powered Stapler
226	Hemostats: Absorbable, with Thrombin
227	Tissue Adhesion Barrier (Absorbable Adhesion Barrier)
228	Sutures with Advanced Material Needles

S.N.	GTE Device/Equipment
229	Antibacterial Knotless Tissue Control Device
230	Embolic Protection Devices
231	Vascular Mimetic Implants
232	Safety Huber Needle
233	Venous Implantable Port/Chemo Ports
234	Polyethylene Seldinger Arterial Catheter with or without Bloodless System
235	Central Venous Catheters: Adult/Paediatric/Neonatal (Antibacterial/Antifungal/ Silver Impregnated)
. 236	Distally Valved Peripherally Inserted Central Catheter
237	Kaolin Based Hemostatic Dressing (Non-absorbable)
238	Flowable Hemostat Gelatin Matrix
239	Resorbable Collagen Based Hemostat
240	Non-invasive Fluid Management Monitoring System
241	Fibrin Sealant with Sythentic Aprotinin
242	Double Lumen Tube with Integrated Camera
243	Acellular Dermal Matrix
244	Intracorporeal Shock Wave Lithotripter:Pneumatic/Dual Energy
245	Thallium Fibre LASER for Stone & Tissue
246	Soft Silicon Flexible Adhesive Four Layered Dressing
247	Reusable Core Biopsy Instrument, with Needles
248	Titanium Bone Mimicking Interbody Spacers for Cervical, PLIF, TLIF, LLIF Procedures
249	K-wireless Minimal Invasive Spinal Fixation System
250	Oxygenators (Adult, Peadiatric, Neonatal)
251	High End (3D) Surgical Loupes with Camera

S.N.	GTE Device/Equipment
252	Microsurgical Instruments for Microvascular Surgeries
253	Mixed Reality/ Augmented Reality/ Virtual Reality (Hardware + Software) for Surgeries
254	Ultra Low Height/Double Abduction Operating Table with Radiolucent Top
255	Advanced 64 Channel EEG Machine
256	Mobile C-arm Angiography System
257	Flat Panel Mobile C-Arm and Fluoroscopy System
258	O-arm Surgical Imaging System
259	Electro-Chemotherapy System
260	HIPEC and Isolated Limb Perfusion Set
261	Hydrogen Peroxide Decontamination System
262	Automated Peritoneal Dialysis Set with Cassette
263	Haemodialysis Machine with Accessories
264	Near Infrared Spectrometer (NIRS)
265	Renal Denervation Therapy
266	Expandable Corpectomy Device
267	Riomimetic Synthetic Absorbable Dural Substitute
268	Gamma Camera with accessories
269	M-Coated Nitinol Hydrophilic Guidewire
270	Three Dimensional Exoscopy and Endoscopy System for Neurosurgery
271	ePTFE Coated Self-expanding Cover Stents
272	Neuro Shunts
273	Dural Graft Substitutes and Sealants
274	Vertebroplasty System with High Viscosity Bone Cement

S.N.	GTE Device/Equipment
275	Cobalt Chromium Vertebral Body Stenting System for Vertebral Compression Fractures
276	Laser Interstitial Ablation (LiTT) for Epilepsy
277	Flexible (3D, 4K) Neuroendoscopic System: Spinal/Skullbase/Ventricular
278	Electrocortigraphy/ Stereo Encephalography Machine with Electrodes and Accessories
279	Cerebral Aneurysm Clips/ Endoscopic Clips for Haemostasis, with Applicators Set
280	Single Head Pressure Injector
281	Digital PET-CT/PET-MR
282	NMR Spectrometer with Electronics and Console
283	Solid-state Cardiac SPECT Camera
284	Fourier Transform NMR System
285	Nucleic Acid Extraction & Quantification System
286	Auto PAP Cervical Cancer Screening System with HIV
287	Electronic Witnessing System for IVF Laboratories
288	Incubator for Culturing Human Gametes and Embryos (incl. Automatic Gas Analyzer)
289	Time Lapse Embryo Imaging System
290	Laser and Imaging System for Human Embryo Biopsy
291	Cryostorage System for Human Embryos and Gametes
292	Stereo Zoom Microscope with Imaging and Documentation System
293	CASA (Computer Assisted Semen Analysis) Equipment
294	Digital Oocyte Aspiration Pump
295	IVF Workstation with Microscope & Imaging System
296	Micromanipulator (Piezo) and Inverted Microscope with Camera, Laser System, Computer etc.
297	Automated Semen Analyzer for Human IVF lab

S.N.	GTE Device/Equipment
298	Tubal Microsurgery Instruments Set
299	LLETZ Unit with Smoke Evacuator with Integrated Cart
300	Digital Refractometer/Auto-Refractometer
301	Fully Automated Non-Contact Tonometer
302	Coaxial Ophthalmoscope (Rechargeable)
303	Digital Non-Mydriatic Fundus Camera
304	Laser Scanning Confocal Microscope
305	LASIK Machine
306	Nd YAG Laser with Accessories
307	Femtosecond Laser Equipment for Lenticule Extraction for Refractive Surgery
308	Femtosecond Laser System for Precision Cataract Surgery
309	Dual Segment/Dual Pump Torsional/ Transversal Phacoemulsification System
310	Thermal Pulsation System for Meibomian Gland Dysfunction
311	Continuous Range of Vision, Toric or Non-Toric, IOLs
312	Optical Coherence Tomography (including console and catheters)
313	Arthroscopy Systems with or without Instruments/Accessories
314	Densitometer with Accessories
315	Variable Angle Plating System for Upper Limb, Lower Limb and Cavicle
316	Femoral Neck Fracture Fixation Set (Min. Invasive/Antirotation Screw/ Trochanteric Femoral Nail)
317	Minimal Invasive Colinear Reduction Clamp with Collinear Sliding Mechanism
318	Damaged Screw & Nail Removal Set with Accessories
319	Biomaterial- Bioactive Glass, Synthetic Bone Graft Substitute
320	Quad Thread Cortical Fix Cement Augmented Fenestrated Screw System

S.N.	GTE Device/Equipment
321	Sweat Collection and Chloride Estimation System
322	Lung Clearance Index Measurement Systems
323	Surfactant Administration Catheter
324	Actigraphy Machine
325	Neuro Developmental Care Incubators for Premature Babies
326	Hybrid Neonatal Warmer cum Incubator Bed for Premature Babies
327	High Frequency Oscillatory Neonatal Ventilator
328	High Flow Nasal Cannula (Paediatric/Neonatal)
329	Animal Stimulator Software for Pharmacology
330	Closed Sterility Test System
331	Drug Discovery Suite
332	In-vivo Animal Imaging System
333	Individually Ventilated Caging Systems for Small Animals
334	Animal Behaviour Monitoring, Tracking and Analysis System
335	Powered Liposuction Set
336	Topical Haemoglobin Spray
337	Body Plethysmograph with Diffusion Study
338	Full Size Inhalation Exposure System
339	Dual Particle Cyclotron
340	Advanced High Energy Linear Accelerator System
341	HDR Brachytherapy
342	DEXA (Dual Energy X-Ray Absorptiometry) Scan
343	CT Scan 256 Slice/Mobile/Intraoperative CT

S.N.	GTE Device/Equipment
344	Tomo-Mammography/Tomosynthesis Guided Breast Biopsy
345	Advanced USG Machine with Shear Wave Elastography and Contrast Enhancement
346	Inferior Vena Cava Filter
347	Advanced Surgical Aspirator
348	Intraoperative Radiotherapy Machines (X-ray based, Flash Machines, Mobile LINAC)
349	Kidney/Liver/Organs Transporter with Expendables for Cadaver Transplant
350	Holimium Laser System with MOSES Technology
351	Percutaneous Nephrolithotomy (PCNL) System
352	Green Light Laser for Photo Vaporization of Prostate
353	Prostatic Urethral Lift
354	Urine Incontinence Implants

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