

**BRIHANMUMBAI MUNICIPAL CORPORATION**

CENTRAL PURCHASE DEPARTMENT

(MEDICINE TENDER SECTION)

No. CPD/Dy.Dean/OD/ 477

**MINUTES OF PREBID MEETING**

Schedule no. IV of 2023-25 (X-ray Films, Chemicals, E.C.G. Rolls, Materials etc.)

**Bid No. 7200043472 (Part 2)**

Pre-bid Meeting for schedule No. IV OF 2023-25 Supply of X-ray Films, Chemicals, E.C.G. Rolls, Materials etc. Bid No. 7200043472 (Part 2) was held on 18.01.2023 at 3.00pm under the Chairmanship of Hon. A.M.C.(W.S.) in Conference Hall, 2<sup>nd</sup> Floor, BMC Head Office.

**Prospective participants are requested to note the following changes:**

1) **GENERAL INSTRUCTIONS TO THE TENDERERS**

**Who can quote : 1.** Tenders will be accepted from Manufacturers / Importers only (Loan License / Third party manufacturing will not be accepted), however he can appoint distributor for supply of goods or can supply directly. Manufacturing firm / importer desires of appointing distributor should mention their names, address, contact no. & email ID in the authority letter of distributor in given proforma as Annexure-22 (Authorized Distributor is authorized to collect the orders, raise the bills for the goods manufactured by manufacturer). Change of distributor within the tender period will not be normally the allowed. However under unavoidable special circumstances as deemed fit by BMC, manufacturer / importer can add/ delete/change authorized distributor maximum on two occasions during the tender process; by payment of Rs. 5,000/- before issuing rate circular or by payment of Rs. 50,000/- when rate circular is in place. **Hence forth Manufacturer / Importer / authorized distributor will be termed as tenderer.** The Manufacturer/ Importer should submit a valid Drug Manufacturing License/Import Lic., FDA Drug Selling License, No Conviction Certificate (Not more than one year old), GST Registration Certificate, Pan Card etc. (as mentioned in the Tender Manual).Tenders received from dealers or any agency/agencies shall be rejected outright.

2) **Packet 'A' Administrative document (MANDATORY)**

**1. Signatures on Packet 'A' Administrative documents :-**

- i. **For Annexure 1 - Physical signature is mandatory in case of Proprietor / Managing Director**
- ii. **For Annexure 1 - All physical signatures advisable in case of 2 Directors / All partners**

**OR**

**Physical signature is mandatory of 1 Director / 1 Partner, Rest all Directors / Partners digital signatures will be accepted.**

- iii. **Rest all Annexures, Physical signature of the signatory mandatory as per tender conditions.**

- 3) Packet 'B' Technical documents (MANDATORY)
- a) Test Report - Test Report from manufacturer / FDA approved laboratory / Govt. aided laboratory /in-house test report from manufacturer duly signed by competent technical staff whose name is mentioned in Valid Drug License **or Competent FDA approved Technical staff.**
- b) Annexure 16 for Manufacturer/ Importer  
**In case of License issued by CDSCO, previous 3 years' Batch count / batch wise production / Import details to be submitted on CA letter head along with market standing certificate issued by MDR Licensing authority.**
- c) Annexure 7  
Annexure 7 in standard tender format **or Subsidiary letter issued by original manufacturer to importer will be accepted.**
- 4) Packet 'A' Administrative document (MANDATORY)  
Annexure 11 (GRIEVANCE REDRESSAL MECHANISM on Letter Head of the Tenderer as per following format)

**Annexure – 11**

SUPPLY OF X-RAY FILMS, CHEMICALS, E. C. G. ROLLS, MATERIELS ETC.

AS PER SCHEDULE NO. IV OF 2023-25 (Bid No. \_\_\_\_\_ ) Part-

**INTERNAL GRIEVANCE REDRESSAL MECHANISM**

1. If a Tenderer is not satisfied with the decision of responsiveness/ non responsiveness in Packets 'A', 'B' or 'C', by the concerned HOD, he may appeal to D.M.C.(C.P.D.) by paying fee of Rs.25,000/- within 7 days from the communication of status of responsiveness / non - responsiveness.
2. D.M.C.(C.P.D.) will assign the work of co-ordination of various activities and administration work to G.C.R. to nominated Registrar – (Retired Sr. Legal Officer, B.M.C.)
3. The Committee for hearing grievances and passing orders will be constituted as follows;
  - (a) The Committee will comprise of D.M.C./ Director/ Jt.M.C. of tender inviting department and D.M.C./ Director / Jt.M.C. of the department for which tender is being invited.  
For example, if tender is invited by C.P.D (MTS) for Public Health & Major Hospitals then the Committee will be of DMC (CPD) and DMC(PH).
  - (b) In case the tender inviting department and department for which tender is being invited are same then the concerned DMC/ Director/ Jt.M.C. of the same department and DMC (CPD) will be the members of the Committee.

For example, if tender is invited by Dean(KEM) for KEM Hospital then the Committee will be DMC (PH) and DMC (CPD).

In tabular format:

<b>Tender inviting Department</b>	<b>Department raising the demand</b>
DMC (CPD) or DMC/ Director / Jt.M.C. of concerned Department	Concerned DMC / Director/ Jt.M.C.

4. In case the work is pertaining to various departments then concerned DMC / Director/ Jt.M.C. having major contribution of work will be one of the members of the Committee.
5. The Committee will hear the grievances of Tenderer within 30 days on receipt of Tenderer's application and will pass an order within 45 days.

If Bidder is not satisfied with the decision of the above Committee, he may appeal to the concerned Addl. Municipal Commissioner of Tender Inviting Department within 3 days from the communication of Internal Grievance Redressal Committee. The Addl. Municipal Commissioner will hear the case within 45 days from the date of receipt of application for second appeal from the bidder and will pass the order within 60 days.

No application shall be maintainable before the Redressal Committee in regard of any decision of the M.C.G.M. relating to following issues:

- Determination of need of procurement
- The decision of whether or not to enter into negotiations.
- Cancellation of a procurement process for certain reasons.

Additional Municipal Commissioner and/or Grievance Redressal Committee, if found, come to the conclusion that any such complaint or review is of vexatious, frivolous or malicious nature and submitted with the intention of delaying or defeating any procurement or causing loss to the procuring entity or any other bidder, then such complainant shall be punished with fine, which may extend to Five Lac rupees or two percent of the value of the procurement, whichever is higher.

**Full Signature of the tenderer  
With Official Seal and Address**

- 5) Changes in specification quantity packing and pre qualifying criteria are shown in below.

**SCHEDULE NO. IV OF 2023-25 (X-RAY FILMS, CHEMICALS, E. C. G. ROLLS, MATERIELS ETC.) Bid No. 7200043472 (Part 2)**

Sr No.	EXISTING DESCRIPTION	REVISED DESCRIPTION	EXISTING PRE-QUALIFYING CRITERIA	REVISED PRE-QUALIFYING CRITERIA
1	2	3	4	5
1	Flavoured, ionic, water soluble, oral contrast agent for G.I. tract for C.T. Combination of Diatrizoate Sodium & Diatrizoate Meglumine. Iodine content 365-375mg/ ml. in 30ml	Flavoured, ionic, water soluble, oral contrast agent for G.I. tract for C.T. Combination of Diatrizoate Sodium & Diatrizoate Meglumine. Iodine content 365-375mg/ ml. in 30ml	1. Drug Mfg. Lic./ Import Lic 2. GMP Cft.	<b>1. Drug Mfg. Lic./ Import Lic</b> <b>2. WHO-GMP Cft./COPP</b> <b>3. Test Report</b>
2	X-RAY EQUIPMENT Lead free air apron, thyroid shield, gonad shield should be ultralight in weight , Mix of Bilayer (Antimony and Bismuth) having area density of 3.2 kg/sqm at 0.25 mm Pb (Not less than 120 cms. Long)	X-RAY EQUIPMENT <b>Lead free apron</b> , thyroid shield, gonad shield should be ultralight in weight , Mix of Bilayer (Antimony and Bismuth) having area density of 3.2 kg/sqm at 0.25 mm Pb (Not less than 120 cms. Long)	1. US FDA Approved. 2. ISO 10993-5:2009 ICMED 13485 BIS Certified	<b>1. Drug Mfg. Lic./ Import Lic</b> <b>2. AERB Approved</b> 3. ISO 10993-5:2009 ICMED 13485 BIS Certified
8	Sterile Braided Angiographic catheters 4F to accept 0.038" guide wire. 100cm long. "Pigtail with multiple side holes	Sterile Braided Angiographic catheters 4F to accept 0.038" guide wire. 100cm long. "Pigtail with multiple side holes	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
9	Sterile Braided Angiographic catheters 4F to accept 0.038" guide wire. 100 cm. long. "H 1"	Sterile Braided Angiographic catheters 4F to accept 0.038" guide wire. 100 cm. long. "H 1"	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
10	Sterile Braided Angiographic catheters 4F to accept 0.038" guide wire. 60 cm. long. "C 1"	Sterile Braided Angiographic catheters 4F to accept 0.038" guide wire. 60 cm. long. "C 1"	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
11	Sterile Braided Angiographic catheters 4F to accept 0.038" guide wire. 100 cm. long. "Sim 1"	Sterile Braided Angiographic catheters 4F to accept 0.038" guide wire. 100 cm. long. "Sim 1"	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.

Sr No.	EXISTING DESCRIPTION	REVISED DESCRIPTION	EXISTING PRE-QUALIFYING CRITERIA	REVISED PRE-QUALIFYING CRITERIA
1  12	2  Sterile Braided Angiographic catheters 5F to accept 0.038" guide wire.100 cm. long. "Sim 1"	3  Sterile Braided Angiographic catheters 5F to accept 0.038" guide wire.100 cm. long. "Sim 1" <b>(PSI above 1000)</b>	4  1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	5  1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
13	Sterile Braided Angiographic catheters 5F to accept 0.038" guide wire. Not less than 60 cm. long. "C 1"	Sterile Braided Angiographic catheters 5F to accept 0.038" guide wire. Not less than 60 cm. long. "C 1"	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
14	Sterile Braided Angiographic catheters 5F to accept 0.038" guide wire. Not less than 60 cm. long. "RDC"	Sterile Braided Angiographic catheters 5F to accept 0.038" guide wire. Not less than 60 cm. long. "RDC"	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
15	Sterile Braided Angiographic catheters 5F to accept 0.038" guide wire. 100 cm. long. "H 1"	Sterile Braided Angiographic catheters 5F to accept 0.038" guide wire. <b>125 cm.</b> long. "H 1"	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
16	Sterile Braided Angiographic catheters 5F to accept 0.038" guide wire. 100cm long. "Pigtail with multiple side holes.	Sterile Braided Angiographic catheters 5F to accept 0.038" guide wire. 100cm long. "Pigtail with multiple side holes.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
17	Vascular Introducer sheath with valve, sidearm, soft dilator & 0.038"/0.035" J. tip guide wire for adults (10 to 13 cm. long) Size 4F (French)	Vascular Introducer sheath with valve, sidearm, soft dilator & 0.038"/0.035" J. tip guide wire for adults (10 to 13 cm. long) Size 4F (French)	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.

Sr No.	EXISTING DESCRIPTION	REVISED DESCRIPTION	EXISTING PRE-QUALIFYING CRITERIA	REVISED PRE-QUALIFYING CRITERIA
1 18	2 Vascular Introducer sheath with valve, sidearm, soft dilator & 0.038"/0.035" J. tip guide wire for adults (10 to 13 cm. long) Size 5F (French)	3 Vascular Introducer sheath with valve, sidearm, soft dilator & 0.038"/0.035" J. tip guide wire for adults (10 to 13 cm. long) Size 5F (French)	4 1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	5 1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
19	Vascular Introducer sheath with valve, sidearm, soft dilator & 0.038"/0.035" J. tip guide wire for adults (10 to 13 cm. long) Size 6F (French)	Vascular Introducer sheath with valve, sidearm, soft dilator & 0.038"/0.035" J. tip guide wire for adults (10 to 13 cm. long) Size 6F (French)	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
20	Vascular Introducer sheath with valve, sidearm, soft dilator & 0.038"/0.035" J. tip guide wire for adults (10 to 13 cm. long) Size 7F (French)	Vascular Introducer sheath with valve, sidearm, soft dilator & 0.038"/0.035" J. tip guide wire for adults (10 to 13 cm. long) Size 7F (French)	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
21	Vascular Introducer sheath with valve, sidearm, soft dilator & 0.038"/0.035" J. tip guide wire for adults (10 to 13 cm. long) Size 8F (French)	Vascular Introducer sheath with valve, sidearm, soft dilator & 0.038"/0.035" J. tip guide wire for adults (10 to 13 cm. long) Size 8F (French)	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
22	Vascular Introducer sheath with valve, sidearm, soft dilator & 0.038"/0.035" J. tip guide wire for adults (10 to 13 cm. long) Size 9F (French)	Vascular Introducer sheath with valve, sidearm, soft dilator & 0.038"/0.035" J. tip guide wire for adults (10 to 13 cm. long) Size 9F (French)	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
23	Vascular Introducer sheath with valve, sidearm, soft dilator & 0.038"/0.035" J. tip guide wire for adults (10 to 13 cm. long) Size 10F (French)	Vascular Introducer sheath with valve, sidearm, soft dilator & 0.038"/0.035" J. tip guide wire for adults (10 to 13 cm. long) Size 10F (French)	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.

Sr No.	EXISTING DESCRIPTION	REVISED DESCRIPTION	EXISTING PRE-QUALIFYING CRITERIA	REVISED PRE-QUALIFYING CRITERIA
1	2	3	4	5
24	Angiographic glide Wire 0.035" angled tip >220 cm long exchange length. (hydrophilic coating)	Angiographic glide Wire 0.035" angled tip >220 cm long exchange length. (hydrophilic coating)	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
25	Angiographic glide wire 0.035" angled tip 145 - 155 cm long (hydrophilic coating)	Angiographic glide wire 0.035" angled tip 145 - 155 cm long (hydrophilic coating)	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
26	Angiographic glide wire 0.035" straight tip 145 - 155 cm long (hydrophilic coating)	Angiographic glide wire 0.035" straight tip 145 - 155 cm long (hydrophilic coating)	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
27	Inj. Non ionic contrast for intravascular use Iodine concentration 300 mg/ml 100 ml Vial.	Inj. Non ionic contrast for intravascular use Iodine concentration 300 mg/ml 100 ml Vial.	1. Drug Mfg. Lic./ Import Lic. 2. Itemwise WHO-GMP Cft. 3. FDA Lab Test Report/ 4. EMA Cft.	1. Drug Mfg. Lic./ Import Lic. 2. Itemwise WHO-GMP Cft./COPP <b>3.USFDA approved OR EU(FDA)</b> <b>4. Test Report</b>
28	Inj. Non ionic contrast for intravascular use Iodine concentration 350-370 mg/ml 100 ml Vial. Or scan Bags packing may be accepted subject to provision of injectors at free cost.	Inj. Non ionic contrast for intravascular use Iodine concentration 350-370 mg/ml 100 ml Vial. Or scan Bags packing may be accepted subject to provision of injectors at free cost.	1. Drug Mfg. Lic./ Import Lic. 2. Itemwise WHO-GMP Cft. 3. FDA Lab Test Report/ 4. EMA Cft.	1. Drug Mfg. Lic./ Import Lic. 2. Itemwise WHO-GMP Cft./COPP <b>3.USFDA approved OR EU(FDA)</b> <b>4. Test Report</b>
29	Inj. Non ionic contrast for intravascular use Iodine concentration 400 mg/ml (100 ml Bottle)	Inj. Non ionic contrast for intravascular use Iodine concentration 400 mg/ml (100 ml Bottle)	1. Drug Mfg. Lic./ Import Lic. 2. Itemwise WHO-GMP Cft. 3. FDA Lab Test Report/ 4. EMA Cft.	1. Drug Mfg. Lic./ Import Lic. 2. Itemwise WHO-GMP Cft./COPP <b>3.USFDA approved OR EU(FDA)</b> <b>4. Test Report</b>
30	Microbubble based Ultrasound contrast media for Radiology/ Cardiology (2D Echo): (Liquid/Powder for Constituting 5 ml volumes)	Microbubble based Ultrasound contrast media for Radiology/ Cardiology (2D Echo): (Liquid/Powder for Constituting 5 ml volumes)	1. Drug Mfg. Lic./ Import Lic. 2. Itemwise WHO-GMP Cft. 3. FDA Lab Test Report 4. EMA Cft.	1. Drug Mfg. Lic./ Import Lic. 2. Itemwise WHO-GMP Cft./COPP <b>3. USFDA approved</b> <b>4. Test Report</b>

Sr No.	EXISTING DESCRIPTION	REVISED DESCRIPTION	EXISTING PRE-QUALIFYING CRITERIA	REVISED PRE-QUALIFYING CRITERIA
1	2	3	4	5
31	Judkin Diagnostic Left Coronary Angiography Catheter Soft tip, atraumatic, 1 to 1 torque control Size 6 f Curve3.5	Judkin Diagnostic Left Coronary Angiography Catheter Soft tip, atraumatic, 1 to 1 torque control Size 6 f Curve3.5	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
32	Judkin Diagnostic Left Coronary Angiography Catheter Soft tip, atraumatic, 1 to 1 torque control Size 6 f Curve4.0	Judkin Diagnostic Left Coronary Angiography Catheter Soft tip, atraumatic, 1 to 1 torque control Size 6 f Curve4.0	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
33	Judkin Diagnostic Left Coronary Angiography Catheter Soft tip, atraumatic, 1 to 1 torque control Size 5 f Curve3.5	Judkin Diagnostic Left Coronary Angiography Catheter Soft tip, atraumatic, 1 to 1 torque control Size 5 f Curve3.5	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
34	Judkin Diagnostic Left Coronary Angiography Catheter Soft tip, atraumatic, 1 to 1 torque control Size 5 f Curve4.0	Judkin Diagnostic Left Coronary Angiography Catheter Soft tip, atraumatic, 1 to 1 torque control Size 5 f Curve4.0	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
35	Judkin Diagnostic Right Coronary Angiography Catheter Soft tip, atraumatic, 1 to 1 torque control Size 6 f Curve3.5	Judkin Diagnostic Right Coronary Angiography Catheter Soft tip, atraumatic, 1 to 1 torque control Size 6 f Curve3.5	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
36	Judkin Diagnostic Right Coronary Angiography Catheter Soft tip, atraumatic, 1 to 1 torque control Size 6 f Curve4.0	Judkin Diagnostic Right Coronary Angiography Catheter Soft tip, atraumatic, 1 to 1 torque control Size 6 f Curve4.0	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
37	Judkin Diagnostic Right Coronary Angiography Catheter Soft tip, atraumatic, 1 to 1 torque control Size 5 f Curve3.5	Judkin Diagnostic Right Coronary Angiography Catheter Soft tip, atraumatic, 1 to 1 torque control Size 5 f Curve3.5	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
38	Judkin Diagnostic Right Coronary Angiography Catheter Soft tip, atraumatic, 1 to 1 torque control Size 5 f Curve4.0	Judkin Diagnostic Right Coronary Angiography Catheter Soft tip, atraumatic, 1 to 1 torque control Size 5 f Curve4.0	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.



Sr No.	EXISTING DESCRIPTION	REVISED DESCRIPTION	EXISTING PRE-QUALIFYING CRITERIA	REVISED PRE-QUALIFYING CRITERIA
1	2	3	4	5
39	Pigtail Angiography catheter with multiple side holes Adult 6F	Pigtail Angiography catheter with multiple side holes Adult 6F	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
40	Pigtail Angiography catheter with multiple side holes Adult 7F	Pigtail Angiography catheter with multiple side holes <b>Adult 5 Fr</b>	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
41	Vascular Introducer sheath with valve, sidearm, soft dilator & 0.021" guide wire with J. tip on one end & straight soft tip on the other end for Paediatrics (7.5 cm long) Size 6F (French)	Vascular Introducer sheath with valve, sidearm, soft dilator & 0.021" guide wire with J. tip on one end & straight soft tip on the other end for Paediatrics (7.5 cm long) Size 6F (French)	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
42	Vascular Introducer sheath with valve, sidearm, soft dilator & 0.021" guide wire with J. tip on one end & straight soft tip on the other end for Paediatrics (min. 7 cm & above long) Size 5F (French)	Vascular Introducer sheath with valve, sidearm, soft dilator & 0.021" guide wire with J. tip on one end & straight soft tip on the other end for Paediatrics (min. 7 cm & above long) Size 5F (French)	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
43	Vascular Introducer sheath with valve, sidearm, soft dilator & 0.021" guide wire with J. tip on one end & straight soft tip on the other end for Paediatrics (min. 7 cm & above long) Size 4F (French)	Vascular Introducer sheath with valve, sidearm, soft dilator & 0.021" guide wire with J. tip on one end & straight soft tip on the other end for Paediatrics (min. 7 cm & above long) Size 4F (French)	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
44	Radiofrequency ablation Catheter 4 mm tip small curve (Green)	Radiofrequency ablation Catheter 4 mm tip small curve (Green)	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.

Sr No.	EXISTING DESCRIPTION	REVISED DESCRIPTION	EXISTING PRE-QUALIFYING CRITERIA	REVISED PRE-QUALIFYING CRITERIA
1	2	3	4	5
45	Radiofrequency ablation Catheter 4 mm tip medium curve (Blue)	Radiofrequency ablation Catheter 4 mm tip medium curve (Blue)	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
46	Diagnostic nondeflatable quadripolar catheter	Diagnostic nondeflatable quadripolar catheter	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
47	Diagnostic deflatable decapolar catheter	Diagnostic deflatable decapolar catheter	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
48	Diagnostic deflatable duodecapolar catheter	Diagnostic deflatable duodecapolar catheter	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
50	Single Length PTFE coated Guide wire 0.038" 'J' tip, (140-210 cm.)	Single Length PTFE coated Guide wire 0.038" 'J' tip, (140-210 cm.)	1. Drug Mfg. Lic./ Import Lic.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
51	Single Length PTFE coated Guide wire 0.035" 'J' tip, (140-210 cm.)	Single Length PTFE coated Guide wire 0.035" 'J' tip, (140-210 cm.)	1. Drug Mfg. Lic./ Import Lic.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
52	Single Length PTFE coated Guide wire 0.032" 'J' tip, (140-210 cm.)	Single Length PTFE coated Guide wire 0.032" 'J' tip, (140-210 cm.)	1. Drug Mfg. Lic./ Import Lic.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
64	NIH cardiovascular catheters with multiple side Holes & closed end made of woven Dacron 6F	NIH cardiovascular catheters with multiple side Holes & closed end made of woven Dacron 6F	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
65	Multipurpose cardiovascular catheters, Soft tip, Atraumatic, 1 to 1 torque control open end without side holes: 6F A-1	Multipurpose cardiovascular catheters, Soft tip, Atraumatic, 1 to 1 torque control open end without side holes: 6F A-1	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.

Sr No.	EXISTING DESCRIPTION	REVISED DESCRIPTION	EXISTING PRE-QUALIFYING CRITERIA	REVISED PRE-QUALIFYING CRITERIA
1	2	3	4	5
66	Diagnostic Amplatz Catheter, Soft tip, Atraumatic, 1 to 1 torque control 6F AL1	Diagnostic Amplatz Catheter, Soft tip, Atraumatic, 1 to 1 torque control 6F AL1	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
67	Diagnostic Amplatz Catheter, Soft tip, Atraumatic, 1 to 1 torque control 5F AR1	Diagnostic Amplatz Catheter, Soft tip, Atraumatic, 1 to 1 torque control 5F AR1	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
68	Diagnostic IMA Catheters, Soft tip, Atraumatic, 1:1 torque control 5F	Diagnostic IMA Catheters, Soft tip, Atraumatic, 1:1 torque control 5F	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
69	Balloon tipped Angiographic catheter 6F	Balloon tipped Angiographic catheter 6F	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
70	Transseptal Mullin's sheath with dilator for Adults. 8F Without sidearm	Transseptal Mullin's sheath with dilator for Adults. 8F Without sidearm	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
71	Transseptal Mullin's sheath with dilator for Paediatrics. 7F Without sidearm	Transseptal Mullin's sheath with dilator for Paediatrics. 7F Without sidearm	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
72	Transseptal needle Adult	Transseptal needle Adult	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
73	Double length (250 to 320 cm) guide wires, PTFE coated with flexible distal tip (J. Tip) With flexible distal tip J tip 0.035"	Double length (250 to 320 cm) guide wires, PTFE coated with flexible distal tip (J. Tip) With flexible distal tip J tip 0.035"	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.

Sr No.	EXISTING DESCRIPTION	REVISED DESCRIPTION	EXISTING PRE-QUALIFYING CRITERIA	REVISED PRE-QUALIFYING CRITERIA
1	2	3	4	5
74	Double length (250 to 320 cm) guide wires, PTFE coated with flexible distal tip (J. Tip) With flexible distal tip J tip 0.032"	Double length (250 to 320 cm) guide wires, PTFE coated with flexible distal tip (J. Tip) With flexible distal tip J tip 0.032"	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
76	Catheter specially designed for angiography through Radial route 5 Fr (1.78 mm) 0.038" Compatible, 100 cm length, tip curve, L shaped with one side hole.	Catheter specially designed for angiography through Radial route 5 Fr (1.78 mm) 0.038" Compatible, 100 cm length, tip curve, L shaped with one side hole.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
77	Vascular Introducer sheath specially designed for angiography through Radial route with valve, side arm, soft dilator & 0.025" Compatible (7 cm long) Size 5Fr	Vascular Introducer sheath specially designed for angiography through Radial route with valve, side arm, soft dilator & 0.025" Compatible (7 cm long) Size 5Fr	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
78	Wire guided triple lumen Biliary/ pancreatic sphincterotome compatible with 0.035" guidewire	Wire guided triple lumen Biliary/ pancreatic sphincterotome compatible with 0.035" guidewire	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
79	Guidewire, hydrophilic coated with flexible tip (straight) 0.035" diameter Minimum 450 cm length	Guidewire, hydrophilic coated with flexible tip (straight) 0.035" diameter Minimum 450 cm length	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
80	Guidewire, hydrophilic coated with flexible tip (curved) 0.035" diameter Minimum 450 cm length	Guidewire, hydrophilic coated with flexible tip (curved) 0.035" diameter Minimum 450 cm length	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.

Sr No.	EXISTING DESCRIPTION	REVISED DESCRIPTION	EXISTING PRE-QUALIFYING CRITERIA	REVISED PRE-QUALIFYING CRITERIA
1	2	3	4	5
81	Guidewire with flexible/hydrophilic tip (straight) 0.025" diameter Minimum 450 cm length .	Guidewire with flexible/hydrophilic tip (straight) 0.025" diameter Minimum 450 cm length .	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
82	Guidewire with flexible/hydrophilic tip (straight) 0.018" diameter Minimum 450 cm length .	Guidewire with flexible/hydrophilic tip (straight) 0.018" diameter Minimum 450 cm length .	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
83	Guidewire fully hydrophilic 0.035" diameter 250 cm	Guidewire fully hydrophilic 0.035" diameter 250 cm	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
84	Guidewire fully hydrophilic 0.025" diameter 250 cm	Guidewire fully hydrophilic 0.025" diameter 250 cm	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
85	Guidewire fully hydrophilic 0.018" diameter 250 cm	Guidewire fully hydrophilic 0.018" diameter 250 cm	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
86	Triple lumen biliary/stone retrieval balloon 1 cm size + 10%	Triple lumen biliary/stone retrieval balloon 1 cm size + 10%	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
87	Triple lumen biliary/stone retrieval balloon 1.5 cm size + 10%.	Triple lumen biliary/stone retrieval balloon 1.5 cm size + 10%.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
88	Triple lumen biliary/stone retrieval balloon 2 cm size +10%	Triple lumen biliary/stone retrieval balloon 2 cm size +10%	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
89	Sclerotherapy needles 21 No min. 200 cm length	Sclerotherapy needles 21 No min. 200 cm length	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	<b>1. Drug Mfg. Lic./ Import Lic.</b>

Sr No.	EXISTING DESCRIPTION	REVISED DESCRIPTION	EXISTING PRE-QUALIFYING CRITERIA	REVISED PRE-QUALIFYING CRITERIA
1	2	3	4	5
90	Triple lumen needle knife biliary sphincterotome	Triple lumen needle knife biliary sphincterotome	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
91	Guiding Catheter 6 F 100 cm	Guiding Catheter 6 F 100 cm	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
94	Disposable Pressure injector syringes 150 ml fast turn syringe with quick fill tube for MARK V/ PROVIS Bayer Medrad injector (DSA)	Disposable Pressure injector syringes 150 ml fast turn syringe with quick fill tube for MARK V/ PROVIS Bayer Medrad injector (DSA)	1. USFDA Approved 2. CE Cft. from notified body	<b>1. Drug Mfg. Lic./ Import Lic.</b> 2. USFDA Approved 3. CE Cft. from notified body
95	5 F Vascular introducer Sheath 7 cm with Hydrophilic 0.025" guide wire in side arm with snap on dilator for radial artery	5 F Vascular introducer Sheath 7 cm with Hydrophilic 0.025" guide wire in side arm with snap on dilator for radial artery	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
96	6 F Vascular introducer Sheath 7 cm with Hydrophilic 0.025" guide wire in side arm with snap on dilator for radial artery	6 F Vascular introducer Sheath 7 cm with Hydrophilic 0.025" guide wire in side arm with snap on dilator for radial artery	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body 3. US FDA Approved.	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
100	EUS Balloons Linear scope	EUS Balloons Linear scope	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
101	EUS Balloons Radial scope	EUS Balloons Radial scope	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
102	Controlled Release Expansion Balloon for esophageal, pyloric, biliary 8, 9 and 10 mm	Controlled Release Expansion Balloon for esophageal, pyloric, biliary 8, 9 and 10 mm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
103	Controlled Release Expansion Balloon for esophageal, pyloric, biliary 10, 11 and 12 mm	Controlled Release Expansion Balloon for esophageal, pyloric, biliary 10, 11 and 12 mm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.

Sr No.	EXISTING DESCRIPTION	REVISED DESCRIPTION	EXISTING PRE-QUALIFYING CRITERIA	REVISED PRE-QUALIFYING CRITERIA
1	2	3	4	5
104	Controlled Release Expansion Balloon for esophageal, pyloric, biliary 12, 13.5 and 15 mm	Controlled Release Expansion Balloon for esophageal, pyloric, biliary 12, 13.5 and 15 mm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
105	Biliary dilator balloon 4 mm	Biliary dilator balloon 4 mm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
106	Biliary dilator balloon 6 mm	Biliary dilator balloon 6 mm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
107	Biliary dilator balloon 8 mm	Biliary dilator balloon 8 mm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
108	Soehendra Biliary dilator 5 F	Soehendra Biliary dilator 6 F	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
109	Soehendra Biliary dilator 7 F	Soehendra Biliary dilator 7 F	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
110	Soehendra Biliary dilator 8 F	Soehendra Biliary dilator 8.5 F	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
111	Soehendra Biliary dilator 10 F	Soehendra Biliary dilator 10 F	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
112	Biliary dilator graded 5, 7 and 10 mm	Biliary dilator graded 5, 7 and 10 mm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
113	CBD Brush cytology	CBD Brush cytology	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
114	Rat tooth forceps	Rat tooth forceps <b>Tender Qty 300</b>	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.

Sr No.	EXISTING DESCRIPTION	REVISED DESCRIPTION	EXISTING PRE-QUALIFYING CRITERIA	REVISED PRE-QUALIFYING CRITERIA
1	2	3	4	5
115	Biopsy forceps with Spike not less than 230 cm	Biopsy forceps with Spike not less than 230 cm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
116	Biopsy forceps without Spike not less than 230 cm	Biopsy forceps without Spike not less than 230 cm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
117	Jumbo Biopsy forceps with Spike not less than 240 cm	Jumbo Biopsy forceps with Spike not less than 240 cm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
118	Jumbo Biopsy forceps Without Spike not less than 240 cm	Jumbo Biopsy forceps Without Spike not less than 240 cm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
119	Plastic Biliary Stent 10 Fr 10 cm	<b>PTFE / Polyurethane</b> Biliary Stent 10 Fr 10 cm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
120	Plastic Biliary Stent 10 Fr 15 cm	<b>PTFE / Polyurethane</b> Biliary Stent 10 Fr 15 cm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
121	Plastic Biliary Stent 10 Fr 12 cm	<b>PTFE / Polyurethane</b> Biliary Stent 10 Fr 12 cm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
122	Plastic Pancreatic Stent 5 Fr 5 cm	<b>PTFE / Polyurethane</b> Pancreatic Stent 5 Fr 5 cm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
123	Plastic Pancreatic Stent 5 Fr 10 cm	PTFE / Polyurethane Pancreatic Stent 5 Fr 10 cm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
124	Plastic Pancreatic Stent 5 Fr 15 cm	PTFE / Polyurethane Pancreatic Stent 5 Fr 15 cm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
125	Plastic Pancreatic Stent 7 Fr 7 cm	PTFE / Polyurethane Pancreatic Stent 7 Fr 7 cm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.



Sr No.	EXISTING DESCRIPTION	REVISED DESCRIPTION	EXISTING PRE-QUALIFYING CRITERIA	REVISED PRE-QUALIFYING CRITERIA
1	2	3	4	5
126	Plastic Pancreatic Stent 7 Fr 10 cm	PTFE / Polyurethane Pancreatic Stent 7 Fr 10 cm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
127	Plastic Pancreatic Stent 7 Fr 15 cm	PTFE / Polyurethane Pancreatic Stent 7 Fr 15 cm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
128	Plastic Biliary Stent 7 Fr 7 cm	PTFE / Polyurethane Biliary Stent 7 Fr 7 cm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
129	Plastic Biliary Stent 7 Fr 10 cm	PTFE / Polyurethane Biliary Stent 7 Fr 10 cm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
130	Plastic Biliary Stent 7 Fr 15 cm	PTFE / Polyurethane Biliary Stent 7 Fr 15 cm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
131	Spring loaded fully automatic and semi automatic biopsy instrument with adjustable penetration depth of 18 mm And 25 mm. Having trocar tip with dimpling on needle and fire ready indicator. 18 g & 25 cm in length	Spring loaded fully <b>automatic</b> biopsy instrument with <b>adjustable penetration depth of 18 mm - 25 mm.</b> Having trocar tip with dimpling on needle and fire ready indicator. 18 g & 25 cm in length	1. USFDA Approved 2. CE cft. from notified body	1. USFDA Approved 2. CE cft. from notified body
132	Angioseal Collagen plug closure Artificial closure device in Radiology and Cardiology procedures Collagen Based plug system Usable up to 8 F punctures	<b>Vascular closure device in Radiology</b> and Cardiology procedures Collagen Based plug system Usable up to 8 F punctures	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
133	Radial Compression device with Dual Comprssion balloons for precise compression of Radial artery without compromising nerve structure	Radial Compression device with Dual Compression balloons for precise compression of Radial artery without compromising nerve structure	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
134	Glide sheath slender with thin wall technology where the outer diameter is reduced by one French size and hydrophilic coating used for complex radial procedures	<b>Slender sheath with thin wall technology</b> where the outer diameter is reduced by one French size and hydrophilic coating used for complex radial procedures	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
135	N-Butyl cyanoacrylate (liquid Glue)	N-Butyl cyanoacrylate (liquid Glue) <b>0.5 ml</b>	1. USFDA Approved 2. CE cft. from notified body	<b>1. Drug Mfg. Lic./ Import Lic.</b>

Sr No.	EXISTING DESCRIPTION	REVISED DESCRIPTION	EXISTING PRE-QUALIFYING CRITERIA	REVISED PRE-QUALIFYING CRITERIA
1	2	3	4	5
136	Straight stent biliary 10f x 7 cm	Straight stent biliary 10f x 7 cm <b>Stents should be made up of PTFE / Polyurethane</b>	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
137	Single pigtail pancreatic stent 5f x 5 cm	Single pigtail pancreatic stent 5f x 5 cm <b>Stents should be made up of PTFE / Polyurethane</b>	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
138	Single pigtail pancreatic stent 5f x 7 cm	Single pigtail pancreatic stent 5f x 7 cm <b>Stents should be made up of PTFE / Polyurethane</b>	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
139	Double pigtail Biliary stent 10f x 7 cm	Double pigtail Biliary stent 10f x 7 cm <b>Stents should be made up of PTFE / Polyurethane</b>	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
140	Double pigtail Biliary stent 10f x 10 cm	Double pigtail Biliary stent 10f x 10 cm <b>Stents should be made up of PTFE / Polyurethane</b>	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
141	Double pigtail Biliary stent 10f x 5 cm	Double pigtail Biliary stent 10f x 5 cm <b>Stents should be made up of PTFE / Polyurethane</b>	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
142	One action stent introduction system	One action stent introduction system	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
143	Hemorrhoidal band ligation system with anoscope	Hemorrhoidal band ligation system with anoscope	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
144	Polypectotomy snare 1.5cm (oval) x 3cm(TF) 240cm	Polypectotomy snare 1.5cm (oval) x 3cm(TF) 240cm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
145	Polypectotomy snare 3 x 6 TF- 240cm oval	Polypectotomy snare 3 x 6 TF- 240cm oval	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
146	Polypectotomy snare Hexagonal 1.5 x 2.5 cm 7f- 240 cm	Polypectotomy snare Hexagonal 1.5 x 2.5 cm 7f- 240 cm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
147	Polypectotomy snare 3 x 4.5cm 7f- 240 cm	Polypectotomy snare 3 x 4.5cm 7f- 240 cm	1. USFDA Approved 2. CE cft. from notified body	1. Drug Mfg. Lic./ Import Lic. 2. CE Cft. from notified body <b>OR</b> 2. US FDA Approved.
148	Inj N-butyl Cyanoactylate (1ml)	Inj N-butyl Cyanoactylate (1ml)	1. USFDA Approved 2. CE cft. from notified body	<b>1. Drug Mfg. Lic./ Import Lic.</b>
<b>Note: itemwise MDR Licence issued by CDSCO &amp; other relevant documents as mentioned in tender manual (Packet B Mandatory Condition) to be submitted wherever applicable. Burden of proof for MDR Licence and other documents lies with the tenderer.</b>				

6. Remaining matter of the tender manual & schedule copy remains the same.

Sd/  
Dy. Dean (CPD)  
Dt. 29.03.2023