FORM MD-40

[See sub-rule (3) of rule 83]

Certificate of registration to Medical Device Testing Laboratory for carry out Test or Evalution of a medical device on behalf of manufacturer

Registration No.: TL/MD/2025/000008

- 1. M/s, Accuprec Research Labs Private Limited situated at Opp. Zydus Pharmez, Changodar-Bavla Highway, Vill-Matoda, Sanand, Ahmedabad, Gujarat 382213 has been registered as a Medical Device Testing Laboratory for carry out Test or Evalution of medical device on behalf of manufacturer under the Medical Devices Rules, 2017.
- 2. Details of medical device(s) to be tested or evaluated.

S.No.	Generic name	Class of medical devices
1	Rectal suction biopsy system (Biocompability Testing as per ISO 10993- 1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4)	Class B
2	Breast, Cervical/intrauterine brachytherapy system applicator, remote- afterloading(Biocompability Testing ISO 10993-1, Sterility Test-IP 2022, Endotoxins Test -USP (161), Phthaletes as per ASTM D7823)	Class C
3	Cervical anaesthesia needle, reusable or single use (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthaletes as per ASTM D7823)	Class B
4	Applicator for bronchial remote afterloading brachytherapy (Biocompability Testing as per ISO 10993- 1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthaletes as per ASTM D7823)	Class C
5	General-purpose ultrasound imaging system (Biocompability Testing as per ISO 10993-1	Class B
6	Blood vessel surgical stripper (Biocompability Testing as per ISO 10993- 1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthaletes as per ASTM D7823)	Class B
7	Neurosurgical ultrasound navigation system (Biocompability Testing as per ISO 10993-1	Class B
8	Hydrophilic, Occlusive, wound dressing (Biocompability Testing as per ISO 10993-1)	Class A
9	Dental dressing forceps, single-use, reusable (Biocompability Testing as per ISO 10993-1)	Class A
10	Umbilical occlusion device (Biocompability Testing as per ISO 10993-1)	Class A

11	Kidney donor-organ preservation/transport system	Class C
	(Biocompability Testing as per ISO 10993-1)	
12	Liquid crystal vein locator (Biocompability	Class B
	Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP	
	(161), Physical test	
13	Colonic mucosa barrier dressing	Class C
	(Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins	
	Test as per USP (161), Phthaletes as per	
	ASTM D7823)	
14	Inhalational analgesia unit (Biocompability	Class B
	Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP	
	(161), Phthaletes as per ASTM D7823)	
15	Biliary/urinary stone retrieval basket,	Class B
	reusable (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022,	
	Endotoxins Test as per USP (161)	
16	Bladder-emptying vibratory stimulator	Class B
	(Biocompability Testing as per ISO 10993-	
	1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161)	
17	Closed-ended wearable urine collection	Class A
	bag, non-sterile (Biocompability Testing as	Class A
	per ISO 10993-1, Sterility Test as per IP	C. Z.
18	2022, Endotoxins Test as per USP (161) Drip, Hand-held Female wearable urinal	Class A
	(Biocompability Testing as per ISO 10993-	Z
	1, Sterility Test as per IP 2022, Endotoxins	0
19	Test as per USP (161) Hand pneumatic lithotripsy system,	Class B
	urinary (Biocompability Testing as per ISO	500
	10993-1, Sterility Test as per IP 2022,	
20	Endotoxins Test as per USP (161) Cervical anaesthesia needle, reusable or	Class B
	single use (Biocompability Testing as per	2
	ISO 10993-1, Sterility Test as per IP 2022,	4
21	Tensile Force as per ISO 7439) Trial lens (Biocompability Testing as per	Class A
	ISO 10993-1)	
22	Incontinence penis clamp, reusable	Class A
	(Biocompability Testing as per ISO 10993- 1, Sterility Test as per IP 2022, Endotoxins	
	Test as per USP (161)	
23	Ureteral patency kit, Cervical anaesthesia	Class B
	kit (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022,	
	Endotoxins Test as per USP (161), Tensile	
	Force as per ISO 7439)	
24	Contraceptive cervical cap, reusable or	Class C
	single use (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022,	
	Tensile Force as per ISO 7439)	
25	Endometrial biopsy kit (Biocompability	Class B
	Testing as per ISO 10993-1, Sterility Test as per IP 2022, Tensile Force as per ISO	
	7439)	
26	Ocular occlude (Biocompability Testing as per ISO 10993-1)	Class A
27	Implantable ligating clip (Biocompability	Class C
	Testing as per ISO 10993-1, Tensile	
28	Strength USP 46-NF) Non-powdered surgeons glove	Class A
	(Biocompability Testing as per ISO 10993-	
	1, Tensile Strength USP 46-NF)	

29	Ablation Device Biocompability Testing as	Class B
	per ISO 10993-1, Sterility Test as per IP	
	2022, Endotoxins Test as per USP (161),	
	Phthalates as per ASTM D7823, Force at	
	break as per IS/ISO 10555-1)	
30	Ablation Device Biocompability Testing as	Class C
	per ISO 10993-1, Sterility Test as per IP	Glade C
	2022, Endotoxins Test as per USP (161),	
	Phthalates as per ASTM D7823, Force at	
0.4	break as per IS/ISO 10555-1)	Olara D
31	Cemented Restrictor (Biocompability	Class B
	Testing as per ISO 10993-1, Sterility Test	
	as per IP 2022, Endotoxins Test as per USP	
	(161)	
32	I.V. Cannula (Biocompability Testing as per	Class A
	ISO 10993-1, Sterility Test as per IP 2022,	
	Endotoxins Test as per USP (161), Blood	
	gas pathway as per ISO 18562-1-2-3,-4,	
	physical test	
33	I.V. Cannula (Biocompability Testing as per	Class B
	ISO 10993-1, Sterility Test as per IP 2022,	
	Endotoxins Test as per USP (161), Blood	
	gas pathway as per ISO 18562-1-2-3,-4,	
	physical test	
34	I.V. Cannula (Biocompability Testing as per	Class C
•	ISO 10993-1, Sterility Test as per IP 2022,	
	Endotoxins Test as per USP (161), Blood	0
	gas pathway as per ISO 18562-1-2-3,-4,	76
	physical test	ORGANIA CHANG
35	Bone Screw (Biocompability Testing as per	Class C
35		Class C
	ISO 10993-1, Sterility Test as per IP 2022,	\equiv
20	Endotoxins Test as per USP (161)	Class D
36	Bone Screw (Biocompability Testing as per	Class D
	ISO 10993-1, Sterility Test as per IP 2022,	
07	Endotoxins Test as per USP (161)	Olasa D
37	Catheter(Biocompability Testing-ISO	Class B
	10993-1, Sterility Test-IP 2022, Endotoxins	abla
	Test- USP (161), Blood gas pathway-ISO	Õ
	ISO 18562-1-2-3,-4, Phthaletes-ASTM	2
	D7823, physical test.	
38	Heart Valve (Biocompability Testing as per	Class D
	ISO 10993-1, Sterility Test as per IP 2022,	7,
	Endotoxins Test as per USP (161),	
	Phthaletes as per ASTM D7823)	
39	Intra Ocular Lenses (Biocompability	Class C
	Testing as per ISO 10993-1, Sterility Test	
	as per IP 2022, Endotoxins Test as per USP	
	(161), Physical test as per ISO 18369-3	
40	Joints (Biocompability Testing as per ISO	Class A
	10993-1, Sterility Test as per IP 2022,	
	Endotoxins Test as per USP (161)	
41	Joints (Biocompability Testing as per ISO	Class B
	10993-1, Sterility Test as per IP 2022,	
<u></u>	Endotoxins Test as per USP (161)	
42	Nail (Biocompability Testing as per ISO	Class C
	10993-1, Sterility Test as per IP 2022,	
<u></u>	Endotoxins Test as per USP (161)	
43	Suture(Biocompability Testing-ISO 10993-	Class A
	1,Tensile Strength-USP 46-NF,Chapter881,	
	Sterility Test-IP 2022, Endotoxins Test-USP	
	(161),Blood gas pathway-ISO 18562-1-2-3,	
	-4,Phthaletes-ASTM D7823,physical test	
44	Suture(Biocompability Testing-ISO 10993-	Class B
""	1,Tensile Strength-USP 46-NF,Chapter881,	Olass D
	Sterility Test-IP 2022, Endotoxins Test-USP	
	(161),Blood gas pathway-ISO 18562-1-2-3,	
	-4,Phthaletes-ASTM D7823,physical test	

45	Suture(Biocompability Testing-ISO 10993-1, Tensile Strength-USP 46-NF, Chapter881,	Class D
	Sterility Test-IP 2022, Endotoxins Test-USP	
	(161),Blood gas pathway-ISO 18562-1-2-3,	
	-4,Phthaletes-ASTM D7823,physical test	
46	Surgical Glove (Biocompability Testing as	Class B
	per ISO 10993-1, Sterility Test as per IP	
	2022, Phthaletes as per ASTM D7823,	
	physical test as per EN 455-1,	
47	Stent (Biocompability Testing as per ISO	Class C
	10993-1, Sterility Test as per IP 2022,	
	Endotoxins Test as per USP (161),	
	Phthaletes as per ASTM D7823)	
48	Plate (Biocompability Testing as per ISO	Class A
	10993-1, Sterility Test as per IP 2022,	
	Endotoxins Test as per USP (161)	
49	Plate (Biocompability Testing as per ISO	Class B
	10993-1, Sterility Test as per IP 2022,	
	Endotoxins Test as per USP (161)	
50	Plate (Biocompability Testing as per ISO	Class C
	10993-1, Sterility Test as per IP 2022,	
	Endotoxins Test as per USP (161)	
51	Mask (Biocompability Testing as per ISO	Class A
	10993-1, Sterility Test as per IP 2022,	
	Resistance to penetration by synthetic	
	blood as per ASTM F 1670, Performance	
	Test as per ASTMF 2100	00
52	Mask (Biocompability Testing as per ISO	Class B
	10993-1, Sterility Test as per IP 2022,	1
	Resistance to penetration by synthetic	5
	blood as per ASTM F 1670, Performance	三
	Test as per ASTMF 2100	Ó.
53	Contact Lens (Biocompability Testing as	Class A
	per ISO 10993-1, Sterility Test as per IP	
	2022, Endotoxins Test as per USP (161),	
54	Physical test as per ISO 18369-3 Contact Lens (Biocompability Testing as	Class B
] 54	per ISO 10993-1, Sterility Test as per IP	Class B
	2022, Endotoxins Test as per USP (161),	Ó
	Physical test as per ISO 18369-3	
55	Neurological Device (Biocompability	Class A
	Testing as per ISO 10993-1)	C Sides !!
56	Neurological Device (Biocompability	Class B
	Testing as per ISO 10993-1)	
57	Neurological Device (Biocompability	Class C
	Testing as per ISO 10993-1)	
58	Neurological Device (Biocompability	Class D
	Testing as per ISO 10993-1)	
59	Wound Care Products (Biocompability	Class A
	Testing as per ISO 10993-1, Tensile	
<u> </u>	Strength as per USP 46-NF, Chapter 881)	
60	Ventilator (Biocompability Testing as per	Class C
	ISO 10993-1, Sterility Test as per IP 2022,	
	Endotoxins Test as per USP (161), Blood	
	gas pathway as per ISO ISO 18562-1-2-3,	
64	-4)	Class C
61	Collagen (Biocompability Testing as per	Class C
62	ISO 10993-1) Blood transfusion set (Biocompability	Class B
02	Testing as per ISO 10993-1, Sterility Test	Class D
	as per IP 2022, Endotoxins Test as per USP	
	(161), Physical test	
63	Coronary artery brachytherapy system	Class D
	applicator (Biocompability Testing as per	0.000 5
	ISO 10993-1, Sterility Test as per IP 2022,	
	Endotoxins Test as per USP (161),	
	Phthaletes as per ASTM D7823)	

64	Disposable Hemoperfusion Cartridge	Class C
	(Biocompability Testing as per ISO 10993-	
	1, Sterility Test as per IP 2022, Endotoxins	
	Test as per USP (161), Physical test	
65	prosthesis (Biocompability Testing as per	Class C
"	ISO 10993-1, Sterility Test as per IP 2022,	01000
66	Endotoxins Test as per USP (161),	Class C
66	Transgingival, Transmandibular implant	Class C
	(Biocompability Testing as per ISO 10993-	
	1, Sterility Test as per IP 2022, Endotoxins	
	Test as per USP (161)	
67	Wearable cervical, lumbar spine traction	Class B
	device implant (Biocompability Testing as	
	per ISO 10993-1)	
68	Manual surgical saw, flexible	Class B
	(Biocompability Testing as per ISO 10993-	
	1, Sterility Test as per IP 2022, Endotoxins	
	Test as per USP (161)	
69	Electromechanical orthopaedic	Class C
""	extracorporeal shock wave therapy system	31433 3
	(Biocompability Testing as per ISO 10993-	
	(Biocompability resting as per 130 10995-	
70	Growth-correction orthopaedic fixation	Class C
70		Class C
	plate kit (Biocompability Testing as per	
	ISO 10993-1, Sterility Test as per IP 2022,	
	Endotoxins Test as per USP (161)	
71	Syringe pump (Biocompability Testing as	Class C
	per ISO 10993-1, Sterility Test as per IP	(C)
	2022, Endotoxins Test as per USP (161),	7/1
	Phthaletes as per ASTM D7823)	
72	Cryosurgical set (Biocompability Testing as	Class C
	per ISO 10993-1, Sterility Test as per IP	\equiv
	2022, Endotoxins Test as per USP (161),	
	Blood gas pathway as per ISO 18562-1-2-	Z
73		Class D
73	3,-4) Coronary artery brachytherapy system	Class D
73	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading	Class D
73	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1,	Al.
73	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP	Al.
73	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO	Al.
	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4)	MONY
73	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge	Al.
	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-	MONY
	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins	MONY
	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway	MONY
74	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO ISO 18562-1-2-3,-4)	Class C
	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO ISO 18562-1-2-3,-4) Absorbent enteric stomal dressing	MONY
74	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO ISO 18562-1-2-3,-4)	Class C
74	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO ISO 18562-1-2-3,-4) Absorbent enteric stomal dressing	Class C
74	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO ISO 18562-1-2-3,-4) Absorbent enteric stomal dressing (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins	Class C
74	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO 1SO 18562-1-2-3,-4) Absorbent enteric stomal dressing (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthaletes as per	Class C
74 75	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO ISO 18562-1-2-3,-4) Absorbent enteric stomal dressing (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthaletes as per ASTM D7823)	Class C Class B
74	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO ISO 18562-1-2-3,-4) Absorbent enteric stomal dressing (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthaletes as per ASTM D7823) Cardiac monitor (including	Class C
74 75	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO ISO 18562-1-2-3,-4) Absorbent enteric stomal dressing (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthaletes as per ASTM D7823) Cardiac monitor (including cardiotachometer and rate alarm)	Class C Class B
74 75	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO ISO 18562-1-2-3,-4) Absorbent enteric stomal dressing (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthaletes as per ASTM D7823) Cardiac monitor (including	Class C Class B
74 75 76	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO ISO 18562-1-2-3,-4) Absorbent enteric stomal dressing (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthaletes as per ASTM D7823) Cardiac monitor (including cardiotachometer and rate alarm) (Biocompability Testing as per ISO 10993-1)	Class B Class B
74 75	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO ISO 18562-1-2-3,-4) Absorbent enteric stomal dressing (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthaletes as per ASTM D7823) Cardiac monitor (including cardiotachometer and rate alarm) (Biocompability Testing as per ISO 10993-1) Intravascular, Transcutaneous blood	Class C Class B
74 75 76	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO ISO 18562-1-2-3,-4) Absorbent enteric stomal dressing (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthaletes as per ASTM D7823) Cardiac monitor (including cardiotachometer and rate alarm) (Biocompability Testing as per ISO 10993-1) Intravascular, Transcutaneous blood gas/pH monitoring system (Biocompability	Class B Class B
74 75 76	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO 1SO 18562-1-2-3,-4) Absorbent enteric stomal dressing (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthaletes as per ASTM D7823) Cardiac monitor (including cardiotachometer and rate alarm) (Biocompability Testing as per ISO 10993-1) Intravascular, Transcutaneous blood gas/pH monitoring system (Biocompability Testing ISO 10993-1, Sterility Test IP 2022,	Class B Class B
74 75 76	3,-4) Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO 1SO 18562-1-2-3,-4) Absorbent enteric stomal dressing (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthaletes as per ASTM D7823) Cardiac monitor (including cardiotachometer and rate alarm) (Biocompability Testing as per ISO 10993-1) Intravascular,Transcutaneous blood gas/pH monitoring system(Biocompability Testing ISO 10993-1, Sterility Test IP 2022, Endotoxins Test as per USP (161), Blood	Class B Class B
74 75 76	Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO ISO 18562-1-2-3,-4) Absorbent enteric stomal dressing (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthaletes as per ASTM D7823) Cardiac monitor (including cardiotachometer and rate alarm) (Biocompability Testing as per ISO 10993-1) Intravascular, Transcutaneous blood gas/pH monitoring system(Biocompability Testing ISO 10993-1, Sterility Test IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4)	Class B Class B Class B
74 75 76	Coronary artery brachytherapy system applicator, manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO ISO 18562-1-2-3,-4) Absorbent enteric stomal dressing (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthaletes as per ASTM D7823) Cardiac monitor (including cardiotachometer and rate alarm) (Biocompability Testing as per ISO 10993-1) Intravascular, Transcutaneous blood gas/pH monitoring system (Biocompability Testing ISO 10993-1, Sterility Test IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Breathing circuit bag (Biocompability	Class B Class B
74 75 76	Coronary artery brachytherapy system applicator, manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO ISO 18562-1-2-3,-4) Absorbent enteric stomal dressing (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthaletes as per ASTM D7823) Cardiac monitor (including cardiotachometer and rate alarm) (Biocompability Testing as per ISO 10993-1) Intravascular, Transcutaneous blood gas/pH monitoring system (Biocompability Testing ISO 10993-1, Sterility Test IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Breathing circuit bag (Biocompability Testing as per ISO 10993-1, Sterility Test	Class B Class B Class B
74 75 76	Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO ISO 18562-1-2-3,-4) Absorbent enteric stomal dressing (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthaletes as per ASTM D7823) Cardiac monitor (including cardiotachometer and rate alarm) (Biocompability Testing as per ISO 10993-1) Intravascular,Transcutaneous blood gas/pH monitoring system(Biocompability Testing ISO 10993-1, Sterility Test IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Breathing circuit bag (Biocompability Testing as per ISO 10993-1, Sterility Test as per USP 19022, Endotoxins Test as per USP 2022, Endotoxins Test as per USP	Class B Class B Class B
74 75 76	Coronary artery brachytherapy system applicator, manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO ISO 18562-1-2-3,-4) Absorbent enteric stomal dressing (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthaletes as per ASTM D7823) Cardiac monitor (including cardiotachometer and rate alarm) (Biocompability Testing as per ISO 10993-1) Intravascular, Transcutaneous blood gas/pH monitoring system (Biocompability Testing ISO 10993-1, Sterility Test IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Breathing circuit bag (Biocompability Testing as per ISO 10993-1, Sterility Test	Class B Class B Class B
74 75 76	Coronary artery brachytherapy system applicator,manual-afterloading (Biocompability Testing-ISO 10993-1, Sterility Test IP 2022, Endotoxins Test -USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Disposable Hemoperfusion Cartridge (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO ISO 18562-1-2-3,-4) Absorbent enteric stomal dressing (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthaletes as per ASTM D7823) Cardiac monitor (including cardiotachometer and rate alarm) (Biocompability Testing as per ISO 10993-1) Intravascular,Transcutaneous blood gas/pH monitoring system(Biocompability Testing ISO 10993-1, Sterility Test IP 2022, Endotoxins Test as per USP (161), Blood gas pathway as per ISO 18562-1-2-3,-4) Breathing circuit bag (Biocompability Testing as per ISO 10993-1, Sterility Test as per USP 19022, Endotoxins Test as per USP 2022, Endotoxins Test as per USP	Class B Class B Class B

79	Annuloplasty, Intracorneal ring.	Class C
1	(Biocompability Testing as per ISO 10993-	0.000
	1, Sterility Test as per IP 2022, Endotoxins	
	Test as per USP (161), Phthaletes as per	
	ASTM D7823, physical test- ISO 18369-3)	
80		Class B
00	Flieringa ophthalmic ring (Biocompability	Class B
	Testing as per ISO 10993-1, Sterility Test	
	as per IP 2022, Endotoxins Test as per USP	
	(161), Physical test	
81		Class B
01	Composite dental impression material	Class B
	(Biocompability Testing as per ISO 10993-	
	1, Sterility Test as per IP 2022, Endotoxins	
	Test as per USP (161)	
82	Dental crown, polymer (Biocompability	Class B
1 02		Oldoo B
	Testing as per ISO 10993-1, Sterility Test	
	as per IP 2022, Endotoxins Test as per USP	
	(161)	
83	Dental impression material	Class A
	(Biocompability Testing as per ISO 10993-	0100071
	1, Sterility Test as per IP 2022, Endotoxins	
<u></u>	Test as per USP (161)	
84	Dental bone matrix implant, animal-	Class C
1	derived (Biocompability Testing as per ISO	
1		
1	10993-1, Sterility Test as per IP 2022,	
	Endotoxins Test as per USP (161)	
85	Carboxymethylcellulose sodium/polymer	Class C
	denture adhesive, zinc-free	Class C
	(Biocompability Testing as per ISO 10993-	70
	1, Sterility Test as per IP 2022, Endotoxins	2
	Test as per USP (161)	
86	Dental amalgam (Biocompability Testing	✓ Class C
	as per ISO 10993-1, Sterility Test as per IP	
07	2022, Endotoxins Test as per USP (161)	Z01 0
87	Bone matrix implant, human-derived	Class C
	(Biocompability Testing as per ISO 10993-	
	1, Sterility Test as per IP 2022, Endotoxins	
	Test as per USP (161)	
88	Collagen dental regeneration membrane	Class C
00		Class C
	(Biocompability Testing as per ISO 10993-	2
	1, Sterility Test as per IP 2022, Endotoxins	
	Test as per USP (161)	O'X
89	Rubber dam clamp forceps	Class A
	(Biocompability Testing as per ISO 10993-	Sidos / (
	1, Sterility Test as per IP 2022, Endotoxins	
<u></u>	Test as per USP (161)	
90	Bite registration rim wax, plate	Class B
1	(Biocompability Testing as per ISO 10993-	
1		
1	1, Sterility Test as per IP 2022, Endotoxins	
	Test as per USP (161)	
91	Ceramic artificial teeth (Biocompability	Class B
1	Testing as per ISO 10993-1, Sterility Test	
1	as per IP 2022, Endotoxins Test as per USP	
1	· ·	
	(161)	21 5
92	Nasal dilator (Biocompability Testing as	Class B
<u></u>	per ISO 10993-1	<u></u> _
93	Tracheal dilator (Biocompability Testing as	Class A
1	per ISO 10993-1	2.3337.
94	Gastrostomy tube (Biocompability Testing	Class C
94		Class C
	as per ISO 10993-1	
95	Vascular, Vena Cava clip (Biocompability	Class B
1	Testing as per ISO 10993-1, Sterility Test	
1	as per IP 2022, Endotoxins Test as per USP	
1	(161), Phthaletes as per ASTM D7823)	
		010
96	Intra-aortic balloon and control system	Class C
	(Biocompability Testing as per ISO 10993-	
	1, Sterility Test as per IP 2022, Endotoxins	
1	Test as per USP (161), Phthaletes as per	
I	· · · · · · · · · · · · · · · · · · ·	
L	ASTM D7823)	

97	Ventricular bypass (assist) device	Class D
	(Biocompability Testing as per ISO 10993-	
	1, Sterility Test as per IP 2022, Endotoxins	
	Test as per USP (161), Phthaletes as per	
	ASTM D7823)	
		0. 5
98	Implantable pacemaker pulse generator	Class D
	(Biocompability Testing as per ISO 10993-	
	1, Sterility Test as per IP 2022, Endotoxins	
	Test as per USP (161), Phthaletes as per	
	ASTM D7823)	
	,	01 0
99	Pacemaker lead adaptor (Biocompability	Class C
	Testing as per ISO 10993-1, Sterility Test	
	as per IP 2022, Endotoxins Test as per USP	
	(161), Phthaletes as per ASTM D7823)	
100	Pacemaker generator function analyser	Class B
	(Biocompability Testing as per ISO 10993-	
	1, Sterility Test as per IP 2022, Endotoxins	
	Test as per USP (161), Phthaletes as per	
1		
	ASTM D7823)	
101	Cardiovascular permanent or temporary	Class B
	pacemaker electrode (Biocompability	
1		
1	Testing as per ISO 10993-1, Sterility Test	
1	as per IP 2022, Endotoxins Test as per USP	
1		
<u> </u>	(161), Phthaletes as per ASTM D7823)	
102	Annuloplasty ring (Biocompability Testing	Class C
1	as per ISO 10993-1, Sterility Test as per IP	
		0.
	2022, Endotoxins Test as per USP (161),	P
	Phthaletes as per ASTM D7823)	.C.
103	Biopsy device (Biocompability Testing as	Class B
1 100		Old33 D
	per ISO 10993-1, Sterility Test as per IP	5
	2022, Endotoxins Test as per USP (161),	\mathbb{Z}_{1}
	Phthaletes as per ASTM D7823)	
101		001 0
104	Extracorporeal circuit and accessories for	Class C
	long-term respiratory/cardiopulmonary	
	failure(Biocompability Testing ISO 10993-	
	1, Sterility Test IP 2022, Endotoxins Test	
	USP (161), Phthaletes ASTM D7823)	
105	External cardiac compressor	Class C
103		Class C
	(Biocompability Testing as per ISO 10993-	7
	1, Sterility Test as per IP 2022, Endotoxins	
	Test as per USP (161), Phthaletes as per	X
		X O
	ASTM D7823)	71
106	External transcutaneous cardiac	Class C
1		0.550
1	pacemaker (Biocompability Testing as per	
1	ISO 10993-1, Sterility Test as per IP 2022,	
1	Endotoxins Test as per USP (161),	
1		
	Phthaletes as per ASTM D7823)	
107	Ear microsystem needle (Biocompability	Class A
	Testing as per ISO 10993-1, Sterility Test	
1		
1	as per IP 2022, Endotoxins Test as per USP	
L	46, Phthaletes as per ASTM D7823)	
108	Epidural/intrathecal anaesthesia kit	Class C
1		0.000
1	(Biocompability Testing as per ISO 10993-	
1	1, Sterility Test as per IP 2022, Endotoxins	
	Test as per USP (161), Phthaletes as per	
1		
4	ASTM D7823)	21 -
109	Removable skin clip (Biocompability	Class B
	Testing as per ISO 10993-1, Tensile	
	Strength USP 46-NF)	
140		Olara D
110	Skin Stapler (Biocompability Testing as per	Class B
	ISO 10993-1, Tensile Strength USP 46-NF)	
111	Lacrimal intubation set (Biocompability	Class C
'''		01033 0
L	Testing as per ISO 10993-1)	
112	Paediatric urine collection/analysis kit	Class A
1	(Biocompability Testing as per ISO 10993-	
1	(Piocompaning results as per 100 10995-	
	1)	

113	Brachytherapy needle (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP 46)	Class C
114	Hollow-fibre haemodialysis dialyser (Biocompability Testing as per ISO 10993- 1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161)	Class C
115	Extracorporeal circuit waste bag (Biocompability Testing as per ISO 10993- 1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161)	Class B
116	Haemodialysis dialysate water chlorine test kit/strip (Biocompability Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161)	Class B



3. This Registration is subject to the conditions as specified in the Drugs and Cosmetics Act,1940(23 of 1940) and the Medical Devices Rules,2017.

Place: New Delhi Central Licensing Authority

Date: 06-May-2025

