



सत्यमेव जयते

FORM MD-40

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

Certificate of registration to Medical Device Testing Laboratory for carry out Test or Evaluation 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 Evaluation 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 (Biocompatibility 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 (Biocompatibility Testing ISO 10993-1, Sterility Test-IP 2022, Endotoxins Test -USP (161), Phthalates as per ASTM D7823)	Class C
3	Cervical anaesthesia needle, reusable or single use (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthalates as per ASTM D7823)	Class B
4	Applicator for bronchial remote afterloading brachytherapy (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthalates as per ASTM D7823)	Class C
5	General-purpose ultrasound imaging system (Biocompatibility Testing as per ISO 10993-1)	Class B
6	Blood vessel surgical stripper (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthalates as per ASTM D7823)	Class B
7	Neurosurgical ultrasound navigation system (Biocompatibility Testing as per ISO 10993-1)	Class B
8	Hydrophilic, Occlusive, wound dressing (Biocompatibility Testing as per ISO 10993-1)	Class A
9	Dental dressing forceps, single-use, reusable (Biocompatibility Testing as per ISO 10993-1)	Class A
10	Umbilical occlusion device (Biocompatibility Testing as per ISO 10993-1)	Class A

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

29	Ablation Device Biocompatibility Testing as 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)	Class B
30	Ablation Device Biocompatibility Testing as 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)	Class C
31	Cemented Restrictor (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161)	Class B
32	I.V. Cannula (Biocompatibility 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, physical test	Class A
33	I.V. Cannula (Biocompatibility 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, physical test	Class B
34	I.V. Cannula (Biocompatibility 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, physical test	Class C
35	Bone Screw (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161)	Class C
36	Bone Screw (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161)	Class D
37	Catheter(Biocompatibility Testing-ISO 10993-1, Sterility Test-IP 2022, Endotoxins Test- USP (161), Blood gas pathway-ISO 18562-1-2-3,-4, Phthalates-ASTM D7823, physical test.	Class B
38	Heart Valve (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthalates as per ASTM D7823)	Class D
39	Intra Ocular Lenses (Biocompatibility 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	Class C
40	Joints (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161)	Class A
41	Joints (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161)	Class B
42	Nail (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161)	Class C
43	Suture(Biocompatibility Testing-ISO 10993-1,Tensile Strength-USP 46-NF,Chapter881, Sterility Test-IP 2022,Endotoxins Test-USP (161),Blood gas pathway-ISO 18562-1-2-3,-4,Phthalates-ASTM D7823,physical test	Class A
44	Suture(Biocompatibility Testing-ISO 10993-1,Tensile Strength-USP 46-NF,Chapter881, Sterility Test-IP 2022,Endotoxins Test-USP (161),Blood gas pathway-ISO 18562-1-2-3,-4,Phthalates-ASTM D7823,physical test	Class B

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

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

79	Annuloplasty, Intracorneal ring. (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthalates as per ASTM D7823, physical test- ISO 18369-3)	Class C
80	Flieringa ophthalmic ring (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Physical test	Class B
81	Composite dental impression material (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161))	Class B
82	Dental crown, polymer (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161))	Class B
83	Dental impression material (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161))	Class A
84	Dental bone matrix implant, animal-derived (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161))	Class C
85	Carboxymethylcellulose sodium/polymer denture adhesive, zinc-free (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161))	Class C
86	Dental amalgam (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161))	Class C
87	Bone matrix implant, human-derived (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161))	Class C
88	Collagen dental regeneration membrane (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161))	Class C
89	Rubber dam clamp forceps (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161))	Class A
90	Bite registration rim wax, plate (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161))	Class B
91	Ceramic artificial teeth (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161))	Class B
92	Nasal dilator (Biocompatibility Testing as per ISO 10993-1)	Class B
93	Tracheal dilator (Biocompatibility Testing as per ISO 10993-1)	Class A
94	Gastrostomy tube (Biocompatibility Testing as per ISO 10993-1)	Class C
95	Vascular, Vena Cava clip (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthalates as per ASTM D7823)	Class B
96	Intra-aortic balloon and control system (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthalates as per ASTM D7823)	Class C

97	Ventricular bypass (assist) device (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthalates as per ASTM D7823)	Class D
98	Implantable pacemaker pulse generator (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthalates as per ASTM D7823)	Class D
99	Pacemaker lead adaptor (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthalates as per ASTM D7823)	Class C
100	Pacemaker generator function analyser (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthalates as per ASTM D7823)	Class B
101	Cardiovascular permanent or temporary pacemaker electrode (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthalates as per ASTM D7823)	Class B
102	Annuloplasty ring (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthalates as per ASTM D7823)	Class C
103	Biopsy device (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthalates as per ASTM D7823)	Class B
104	Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure (Biocompatibility Testing ISO 10993-1, Sterility Test IP 2022, Endotoxins Test USP (161), Phthalates ASTM D7823)	Class C
105	External cardiac compressor (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthalates as per ASTM D7823)	Class C
106	External transcutaneous cardiac pacemaker (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthalates as per ASTM D7823)	Class C
107	Ear microsystem needle (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP 46, Phthalates as per ASTM D7823)	Class A
108	Epidural/intrathecal anaesthesia kit (Biocompatibility Testing as per ISO 10993-1, Sterility Test as per IP 2022, Endotoxins Test as per USP (161), Phthalates as per ASTM D7823)	Class C
109	Removable skin clip (Biocompatibility Testing as per ISO 10993-1, Tensile Strength USP 46-NF)	Class B
110	Skin Stapler (Biocompatibility Testing as per ISO 10993-1, Tensile Strength USP 46-NF)	Class B
111	Lacrimal intubation set (Biocompatibility Testing as per ISO 10993-1)	Class C
112	Paediatric urine collection/analysis kit (Biocompatibility Testing as per ISO 10993-1)	Class A

113	Brachytherapy needle (Biocompatibility 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 (Biocompatibility 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 (Biocompatibility 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 (Biocompatibility 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

