



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/2025/000007

1. M/s, **MDR Laboratories Private Limited** situated at **No, 444 Gokulam Street, Mathur, Manali, , Ambattur, Tiruvallur, Tamil Nadu - 600068** 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	External prostheses, Fixation tapes, Bandages (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class A
2	Surgical gloves, Occlusive patches for ulcers (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
3	Equipment covers, Probe covers, Bed cover, Fabrics (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class A
4	Diagnostic kit/Devices, Examination devices (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class A
5	Skin care devices, Electrodes (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class A
6	Wound dressing or healing devices, Stimulator (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
7	Wound care gels-cream-powders (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B

8	Surgical gowns, Gloves, Drapes, Wipes, Cream (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class A
9	Biological sample collection bag and container (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
10	Extension sets, Transfer sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
11	Ophthalmic solutions, Contact lens solutions (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class B
12	GGloves, Probe covers (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
13	Ocular devices, Surgical implements (Biocompatibility as per ISO 10993-Parts3, 4,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part18,SOP ANA-011,ANA-012,ANA-013)	Class B
14	Dental resin, Dental filling materials (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class C
15	Dental products, Dental implants (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class C
16	Internal drug delivery catheters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class C
17	Packaging materials, Collagen (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class C
18	Polymers like nylon, Polystyrene (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class C

19	Polyethylene (linear), Polypropylene (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class C
20	Replacement joints, Bone prostheses (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class D
21	Pacemakers, Artificial larynxes (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class D
22	Dental implants (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011, ANA-012,ANA-013)	Class D
23	Pacemaker electrodes, Dialysers (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class C
24	Extracorporeal devices and accessories (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012,ANA-013)	Class C
25	Surgical implements (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
26	Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
27	Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class A
28	Monitoring devices, Transdermal patch, Gel (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class A
29	Sensor, Personal protective equipment, Masks (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class A
30	Skin contacting devices, non-invasive electrodes (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class A

31	Burns and granulation tissue (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
32	Laparoscopes, Arthroscopes, Endoscopes (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
33	Blood administration sets, Filters (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23,USP-87,88,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
34	Irrigation set, Intravenous sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23,USP-87,88,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
35	Blood collections sets, Bags (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23,USP-87,88,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
36	Needles, Syringes (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
37	Surgical instruments, Urological devices (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
38	Cardiovascular devices, Surgical accessories (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012, ANA-013)	Class B
39	Respiratory devices, Neurological devices (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
40	Gynaecological devices (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
41	Skin staples, Dentistry devices (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
42	Devices contacting mucosal membrane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B

43	Intravaginal devices, Vaginal pad (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
44	Menstrual pad, Orthodontic devices (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
45	Finger cot, Eye care device (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
46	Catheters, Guide wire, Oxygenators (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class B
47	Blood tubing, Urological devices (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class B
48	Respiratory devices, Catheters, (Biocompatibility as per ISO 10993-Parts3, 4,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part18,SOP ANA-011,ANA-012,ANA-013)	Class B
49	Gastrointestinal devices, Tubes (Biocompatibility as per ISO 10993-Parts3, 4,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part18,SOP ANA-011,ANA-012,ANA-013)	Class B
50	Electrodes, Gynaecological devices (Biocompatibility as per ISO 10993-Parts3, 4,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part18,SOP ANA-011,ANA-012,ANA-013)	Class B
51	Haematological devices (Biocompatibility as per ISO 10993-Parts3,4,5,6,10,11,23, USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part18, SOP ANA-011,ANA-012,ANA-013)	Class B
52	Health monitoring sensors (Biocompatibility as per ISO 10993-Parts3, 4,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part18,SOP ANA-011,ANA-012,ANA-013)	Class B
53	Neuromuscular sensors and stimulators (Biocompatibility as per ISO10993-Parts3, 4,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO10993-Part18,SOP ANA-011,ANA-012, ANA-013)	Class B

54	Devices contacting mucosal membrane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class C
55	Contraceptives, Personal lubricants (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class C
56	Contact lenses, Urinary catheters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class C
57	Intra intestinal devices, Menstrual cups (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class C
58	Endotracheal tubes, Bronchoscopes (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class C
59	Dental prostheses, Intrauterine device (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class C
60	Gastrointestinal devices (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class C
61	Draining systems, Dental cements (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class C
62	Dialysis tubing and accessories (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class C
63	Hemoabsorbents, Immunoabsorbents (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class C
64	Incubator, Neurological devices (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88,151, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class C

65	Sutures, Intraocular lens(IOL), Ligation clips (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class C
66	Drug delivery devices, Replacement tendons (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class C
67	Breast implants, Intrauterine devices (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class C
68	Hearing aid and implant, cochlear implant (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class C
69	Ventricular assist devices (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)	Class C
70	Raw Ingredients, Container systems (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class C
71	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)	Class C
72	Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class C
73	Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class C
74	Resins, Medical device extracts (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class C
75	Cardiovascular devices (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)	Class D
76	Orthopedic pins, Plates, Screws (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class D

77	Bone cements and Intraosseous devices (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class D
78	Subperiosteal implants, Implants (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class D
79	Orthopaedic implants, Ocular implants (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class D



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: 16-Apr-2025

