



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/2024/000018

1. M/s, **RIBOSOME RESEARCH CENTRE PRIVATE LIMITED** situated at **SR.NO. 261/1, BLOCK NO. 271, NEAR DHANVANTARY PHARMACY COLLEGE, VILLAGE - KUDSAD, TAL.-OLPAD, OLPAD, Surat, Gujarat - 394110** 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	Intra Ocular Implants - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33) and ASTM.	Class D
2	Heart Valves - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33) and ASTM.	Class D
3	Ablation Device - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33) and ASTM.	Class D
4	Vascular devices, IV sets, Cannulae and Scalp Vein Set, Perfusion Sets - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33) and ASTM. Sterility BET MLT as per IP BP USP and other standards	Class D
5	Tubular rings - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33) and ASTM. Sterility BET MLT as per IP BP USP and other standards	Class C
6	Copper T - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33) and ASTM. Sterility BET MLT as per IP BP USP and other standards	Class C
7	Sutures - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33) and ASTM.	Class C
8	Syringes - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33) and ASTM.	Class B
9	Orthopaedic Devices, Joints, Screws and Plates - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33) and ASTM.	Class C
10	Internal Prosthetic Replacements - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33) and ASTM.	Class D
11	Low Density Polyethylene, High Density Polyethylene, Rubber Stoppers, Elastomeric Rubbers - Cytotoxicity as per USP 42, Chapter 87	Class A
12	Condoms - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33) and ASTM. Sterility BET MLT as per IP BP USP and other standards	Class C
13	Blood Bags and other Medical Devices - Sterility BET MLT as per IP BP USP and other standards	Class B

14	Surgical Gloves and Dressings - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33) and ASTM.	Class B
15	Cardiac Stents (including Drug Eluting Stents) - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33) and ASTM.	Class D
16	Catheters - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33) and ASTM. Sterility BET MLT as per IP BP USP and other standards	Class B
17	Bone Cements - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33) and ASTM.	Class C
18	Needles - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33) and ASTM. Sterility BET MLT as per IP BP USP and other standards	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

Date: 05-Sep-2024

Central Licensing Authority

