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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/2026/000015

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	Leprosopic Devices - Oral Mucosa Irritation Test as per ISO 10993 - 23.	Class B
2	Intra Ocular Implants - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class D
3	Tubal Ring- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class C
4	Sutures- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class C
5	Orthopaedic Devices, Joints, Screw and Plates- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class C
6	Sutures- All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
7	Modular Cup- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class C
8	Surgical Instrument Metals and Accessories- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class B
9	Surgical Blades- All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
10	Surgical Blades- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class B
11	Rhinology Product- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
12	Respiratory Devices - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
13	Respiratory Devices - Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
14	Paediatric Devices - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
15	Gastrointestinal Devices - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
16	Gastrointestinal Devices - Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class B
17	Dental Tools- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class B
18	Surgical Instrument Metals and Accessories- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class B

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19	Surgical Instrument Metals and Accessories- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class A
20	Biopsy Punches- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class A
21	Syringe with Needles - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
22	Syringe with Needles - Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class B
23	Infusion Sets- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class B
24	Blood Pressure Monitoring Device - Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class B
25	Eye Drops and Ophthalmic Temponades- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class A
26	Umbilical Tapes - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class A
27	Urological Devices - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class A
28	Umbilical Tapes - Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class A
29	Organ Preservative Solution - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
30	Glucometer (Syringe of lancet) - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
31	Digital Thermometer - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
32	Disinfectant specified on Medical Device - All Biocompatibility tests - ISO 10993 (1 to 18, 23, 33).	Class B
33	Surgical Implements - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
34	Ventilators - Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
35	Anesthesiology - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
36	Interventional and Radiology - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
37	Oncology - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
38	Radiotherapy - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
39	Nephrology - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
40	Renal care - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
41	Stromal Vascular Fraction and Platelet Rich Plasma - All Biocompatibility tests - ISO 10993 (1 to 18, 23, 33).	Class B
42	Blood Bags, other Medical Devices- All Biocompatibility tests - ISO 10993 (1to18, 23,33).	Class C
43	Scalp Vein Set - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
44	All Implantable Medical Device Equipment - All Biocompatibility tests - ISO 10993 (1 to 18, 23, 33).	Class C
45	Gynaecological Devices - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
46	Heamatological Devices - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
47	Anesthesiology - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class A

48	Anesthesiology - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
49	Pain Management - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
50	Pain Management - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
51	Cardiovascular - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
52	Leprosic Devices - Oral Mucosa Irritation Test as per ISO 10993 - 23.	Class A
53	Leprosic Devices - Oral Mucosa Irritation Test as per ISO 10993 - 23.	Class C
54	Ablation Device- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class D
55	Ablation Device- All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class D
56	Ablation Device - Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class D
57	Tubular Rings- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class C
58	Copper T- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class C
59	Copper T- All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
60	Copper T- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
61	Intra Ocular Implants - Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class D
62	Heart Valves- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class D
63	Heart Valves- All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class D
64	Heart Valves - Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class D
65	Vascular Device- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class B
66	Vascular Device- All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
67	Vascular Device- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class B
68	Tubular Rings- All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
69	Contraceptive Products- All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
70	Personal Protective Equipment (PPEs)- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class A
71	Ophthalmic Implants- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class C
72	Stent Device- All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class D
73	Stent Device- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class D
74	Dental implants- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class C
75	Dental implants- All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
76	Dental implants- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
77	Urological device- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class A
78	Urological device- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class A
79	Urological device- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class B
80	Urological device- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class B

81	Gynecological Device- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class C
82	Gynecological Device- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
83	Ear, Nose, Throat (ENT) Device/ENT Implant- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class C
84	Sterile Tips and centrifuge Tubes- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class B
85	Surgical Gauze and Dressing- All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class A
86	Modular Cup- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
87	Cement Restrictor- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class A
88	Cement Restrictor- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class A
89	Nodular Head- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class C
90	Neurological device- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class C
91	Neurological device- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class D
92	Neurological device- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class D
93	Surgical Blades- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class B
94	Vein Set- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class B
95	Paediatric Devices - Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
96	Middle Ear Implants- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class D
97	Laryngectomy Implant- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class D
98	Ear Ventilation Tube- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
99	Scalpels and sharps- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class A
100	Scalpels and sharps- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class B
101	Scissors- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class A
102	Clamps and Crimpers- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class A
103	Dental Tools- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class A
104	Condoms- All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
105	Condoms- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
106	Blood Bags and other Medical Devices- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class C
107	Cardiac/Coronary Stents- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class D
108	Cardiac/Coronary Stents- All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class D
109	Cardiac/Coronary Stents- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class D
110	Catheters- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class B
111	Catheters- All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B

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112	Bone Cements- All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
113	Bone Cements- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
114	Needles- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class B
115	Surgical Gauze and Dressing- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class A
116	Surgical Gauze and Dressing- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class B
117	Surgical Gauze and Dressing- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class A
118	Surgical Gauze and Dressing- All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
119	Uncemented Femoral Stem- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class C
120	Nodular Head- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
121	Neurological device- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
122	Surgical Instrument Metals and Accessories- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class A
123	Sutures- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
124	Hypodermic Syringes- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class B
125	Hypodermic Syringes- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class B
126	Internal Prosthetic Replacements - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class D
127	Internal Prosthetic Replacements - Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class D
128	Condoms- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class C
129	Blood Bags and other Medical Devices- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
130	Surgical Gloves and Dressings - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
131	Surgical Gloves and Dressings - Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class B
132	Catheters- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class B
133	Bone Cements- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class C
134	IV set and BT set- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class B
135	IV set and BT set- All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
136	IV set and BT set- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class B
137	Contraceptive Products- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class C
138	Contraceptive Products- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
139	Personal Protective Equipment (PPEs)- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class A
140	Ophthalmic Implants- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
141	Ophthalmic Implants- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class D

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142	Ophthalmic Implants- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class D
143	Stent Device- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class D
144	Ear, Nose, Throat (ENT) Device/ENT Implant- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
145	IV Cannula - BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class B
146	IV Cannula - Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class B
147	Sterile Tips and centrifuge Tubes- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class B
148	Wound Care Products - BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class C
149	Wound Care Products - Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
150	Surgical Gauze and Dressing- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class B
151	Nails- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class C
152	Disposable Perfusion Set- BET, Sterility, MLT, Pathogen Testing as per IP, BP, USP.	Class B
153	Disposable Perfusion Set- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class B
154	Nebulizer - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
155	Nebulizer - Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
156	Blood Component Bag- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
157	Blood Pressure Monitoring Device - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
158	Eye Drops and Ophthalmic Temponades- Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class B
159	Blood Gas Pathways - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
160	Blood Gas Pathways - Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
161	Urological Devices - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
162	Neurological Devices - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
163	Neurological Devices - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class D
164	Heamatological Devices - Ethylene Oxide and Ethylene Chlorohydrin as per ISO 10993-7.	Class C
165	Ventilators - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
166	Pain Management - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class A
167	Pain Management - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class D
168	Cardiovascular - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
169	General Hospital - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
170	Obsterical - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class A
171	Obsterical - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B

172	Obsterical - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
173	Ophthalmic - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
174	Rehabilitation - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
175	Interventional and Radiology - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
176	Nephrology - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
177	Renal care - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
178	Dental Products - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
179	Throat Products - Oral Mucosa Irritation Test as per ISO 10993 - 23.	Class A
180	Throat Products - Oral Mucosa Irritation Test as per ISO 10993 - 23.	Class B
181	Reconstructive Surgery Products - Oral Mucosa Irritation Test as per ISO 10993 - 23.	Class C
182	General Hospital - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class A
183	Operation Theater (OT) - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
184	Operation Theater (OT) - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class D
185	Rehabilitation - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class A
186	Rehabilitation - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
187	Interventional and Radiology - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class A
188	Interventional and Radiology - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class B
189	Dermatology and Plastic Surgery - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
190	Oncology - All Biocompatibility tests as per ISO 10993 (1 to 18, 23, 33).	Class C
191	Orthopaedic Devices, Joints, Screw, Plates- All Biocompatibility tests - ISO 10993 (1to18,23,33).	Class C
192	Orthopaedic Devices, Joints, Screw, Plates- Ethylene Oxide, Ethylene Chlorohydrin - ISO 10993-7.	Class C
193	Personal Protective Equipment- All Biocompatibility tests - ISO 10993 (1to18, 23,33).	Class A
194	Ear,Nose,Throat (ENT) Device/ENT Implant- All Biocompatibility tests - ISO 10993 (1to18,23,33).	Class C
195	Surgical Instrument Metals, Accessories- All Biocompatibility tests - ISO 10993 (1to18,23,33).	Class A
196	Surgical Instrument Metals, Accessories- All Biocompatibility tests - ISO 10993 (1to18,23,33).	Class B
197	Eye Drops, Ophthalmic Temponades- All Biocompatibility tests-ISO 10993 (1to18, 23,33).	Class A
198	Eye Drops, Ophthalmic Temponades- All Biocompatibility tests-ISO 10993 (1to18, 23,33).	Class B

199	Contact lens, lens Care Products - All Biocompatibility tests-ISO 10993 (1to18, 23,33).	Class A
200	Contact lens, lens Care Products - All Biocompatibility tests-ISO 10993 (1to18, 23,33).	Class B
201	Pediatric,Neonatology Medical - All Biocompatibility tests-ISO 10993 (1to18, 23,33).	Class B

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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.

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Central Licensing Authority

