



[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/2021/000005

1. M/s, Shiva Analyticals (India) Private Limited situated at Plot Nos. 24D (P) & 34D, KIADB Industrial Area, Hoskote, Bangalore, Hoskote, Bengaluru (Bangalore) Rural, Karnataka - 562114 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	Cardiac Stents (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class D
2	Catheters (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class C
3	Catheters (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class D
4	Disposable Perfusion Sets (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class C
5	Drug Eluting Stents (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class D
6	Heart Valves (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class D
7	Intra Ocular Lenses (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class C
8	IV Cannula (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class C
9	Orthopaedic Implants (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class B
10	Orthopaedic Implants (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class C

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2017年12月, 中国内地共发生20起道路交通事故, 造成10人死亡、10人受伤、10辆机动车受损。其中, 2017年12月10日, 在广州市天河区, 发生一起严重的交通事故, 造成1人死亡、1人受伤、1辆机动车受损。

1 1	Scalp Vein Set (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class B
12	Surgical Dressings (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class A
13	Surgical Dressings (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class B
14	Surgical Dressings (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class C
15	Ablation Device (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class D
16	Cardiac Stents (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class C
17	Catheters (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class A
18	Catheters (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class B
19	Disposable Hypodermic Needles (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class B
20	Disposable Hypodermic Syringes (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class B
21	Disposable Hypodermic Syringes (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class C
22	Disposable Perfusion Sets (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class A
23	Disposable Perfusion Sets (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class B
24	IV Cannula (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class B
25	Orthopaedic Implants (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class D
26	Surgical Dressings (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class D

27	Ablation Device (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008)	Class C
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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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