



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/2024/000011

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	Cap (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class A
2	Cap (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class B
3	Cap (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class C
4	Cap (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class D
5	Bottle (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class A
6	Bottle (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class B
7	Bottle (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class C
8	Nozzle (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class A
9	Nozzle (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class B
10	Nozzle (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class C
11	Surgical Gown (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class A

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ORGANISATION, ou=CENTRAL DRUGS STANDARD CONTROL
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12	Surgical Gown (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class B
13	Needles (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class A
14	Needles (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class B
15	Needles (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class C
16	Needles (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class D
17	Cotton Gauze (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class A
18	Cotton Gauze (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class B
19	Surgical Dressing Swab (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class A
20	Surgical Dressing Swab (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class B
21	Gloves (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class A
22	Gloves (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class B
23	Drape (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class A
24	Drape (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class B
25	Drape (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class C
26	Drape (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class D
27	Catheters (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class A
28	Catheters (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class B

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29	Catheters (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class C
30	Catheters (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class D
31	Sutures (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class C
32	Sutures (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class A
33	Sutures (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class B
34	Sutures (Test - Bioburden Test , Sterility Test and Bacterial Endotoxin Test, Standard/Specification - ISO 11737-1-2018, ISO 11737-2-2019 and USP-85-2023)	Class D

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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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Place: New Delhi

Date: 01-Aug-2024

Central Licensing Authority

