



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/2024/000008

1. M/s, BIO VISION MEDICAL SYSTEMS situated at No.49 & 50, 2nd Floor, Samuvel Nagar, Vadaperumbakkam, Chennai, Chennai, Tamil Nadu - 600060 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	Steam sterilizer / Autoclave - Temperature, Pressure - IEC 61010-2-040	Class C
2	Foetal pulse oximeter/ Pulse Oximeter/ Pulse oximetry telemetric monitoring system - SpO2, Pulse Rate - ISO 80601-2- 61	Class B
3	Thoracic suction pump - Vacuum Pressure - ISO 10079-1	Class B
4	Medical Gas Flowmeter -Flow - ISO 8185/ISO 9360- 1/62353	Class A
5	Electrosurgical Unit - Power, Current, REM Test - IEC 60601-2-2	Class C
6	Neonatal CPAP - Pressure (PEEP,PIP, MAP), Respiration Rate, Volume (Tidal, Minute), Time (Insp, Exp), FiO2, Flow - IEC 60601-2-12, ISO 80601-2-12	Class C
7	Nebuliser - Flow - ISO 27427	Class B
8	Syringe pump - Flow, Volume, Occlusion - IEC 60601-2-24	Class C
9	Infusion pump - Flow, Volume, Occlusion - IEC 60601-2-24	Class C
10	Boiling water sterilizer - Temperature - IEC 61010-2- 040	Class B
1 1	BPAP unit - Pressure (IPAP, EPAP), RR, Vol (Tidal, Minute), Time(Insp, Exp)/IE Ratio - IEC 60601-2-12	Class B
12	Airway Pressure/Oxygen Monitor - IEC 60601-2-12	Class B

13	Ventilator/ Neonatal Ventilator - Pressure (PEEP,PIP,MAP), Respiration Rate, Volume (Tidal, Minute), Time (Insp, Exp), FiO2, Flow - IEC 60601-2-12, IEC 60601-2-13, ISO 80601-2-12, ISO 80601-2-13	Class C
14	Tourniquet - Pressure - BS 7088	Class B
15	Foetal Doppler system/CTG/Fetal Monitors - Heart Rate (Fetal, Maternal), Amplitude (Fetal, Maternal) - IEC60601-2-37, IEC 61266	Class C
16	Anesthesia Machine - Pressure (PEEP,PIP, MAP), Respiration Rate, Volume (Tidal, Minute), Time (Insp, Exp), FiO2, Flow - IEC 60601-2-12, IEC 60601-2-13, ISO 80601-2-12, ISO 80601-2-13	Class C
17	High frequency Ventilator - Pressure (PEEP,PIP,MAP), Respiration Rate, Volume(Tidal, Minute),Time (Insp, Exp), FiO2, Flow-ISO 80601-2-87, IEC 60601-2-12, IEC 60601-2-13, ISO 80601-2-12, ISO 80601-2-13	Class C
18	BP Apparatus/BP Monitors - Pressure - IEC 80601-2-30	Class B
19	Pacemaker generator function analyzer - IEC 60601-2-31, IEC 61010-1	Class C
20	Oxygen Concentrator - Flow, FiO2 - ISO 80601-2-69	Class B
21	Infant incubator - Temperature, RH, Sound - IEC 60601-2-19	Class C
22	Transport infant incubator - Temperature, RH, Sound - IEC 60601-2-20	Class C
23	Open infant incubator - Temperature, RH, Sound - IEC 60601-2-19	Class C
24	Infant warmer - Temperature - IEC 60601-2-21	Class C
25	Ventilator/Neonatal Ventilator - Pressure (PEEP,PIP,MAP), Respiration Rate, Volume (Tidal, Minute), Time (Insp, Exp), FiO2, Flow - IEC 60601-2-12, IEC 60601-2-13, ISO 80601-2-12, ISO 80601-2-13	Class C
26	Pacing system analyzer - IEC 60601-2-31, IEC 61010-1	Class C
27	Patient Physiologic Monitoring System/ Neonatal physiologic monitoring system - IEC 80601-2-49, IEC 60601-2-27, ISO 80601-2-61, IEC 60601-2-34	Class C
28	Phototherapy unit - Irradiance - IEC 60601-2-50	Class B
29	Defibrillator - Energy, ECG HR, ECG Amplitude, Pacer Amplitude, Pacer Rate - IEC 60601-2-4	Class C

30	Blanket/pad infant phototherapy unit tester - Irradiance - IEC 60601-2-50, IEC 61010-1	Class B
31	Electrocardiograph - ECG Amplitude, Heart rate - IEC 60601-2-25/IEC 60601-2-27/ IEC 60601-2-47	Class B
32	External transcutaneous cardiac pacemaker - Pacer Rate, Pacer Amplitude - IEC 60601-2-31	Class C
33	Pulse Oximeter - SpO ₂ , Pulse Rate - ISO 80601-2-61	Class C
34	Oxygen Saturation/Pulse Rate Simulator - SpO ₂ , Pulse Rate - ISO 80601-2-61, IEC 61010-1	Class A



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: 18-Jun-2024

Central Licensing Authority

