

Laboratory Astute Labs Pvt. Ltd., Sr. No. 82/1, Bajirao Dhawade Patil Industrial Estate, NDA Road, Shivane, Pune, Maharashtra

Accreditation Standard ISO/IEC 17025: 2005

Certificate Number TC-5365

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Validity 27.03.2017 to 26.03.2019

Last Amended on --

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
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ELECTRONICS TESTING

I.	PERFORMANCE/DURABILITY/ SAFETY TEST			
1.	Medical electrical equipment-General	Power Input	IEC 60601-1, Ed.3.1 EN 60601-1, Ed.3 Cl.no.4.11	10 V to 300 V AC 0.1mA to 16 A Upto 50 Hz
		Applied parts and accessible parts	IEC 60601-1, Ed.3.1 EN 60601-1, Ed.3: 2006 Cl.no. 5.9	Test finger 12mm, Test hook 180x 5x1mm
		Identification, marking and documents	IEC 60601-1, Ed.3.1 EN 60601-1, Ed.3 Cl.no.7	Qualitative
		Intended to be connected to a power source by a plug	IEC 60601-1, Ed.3.1 EN 60601-1, Ed.3 Cl.no.8.4.3	1 V to 230 V AC Upto 50 Hz
		Protective earthing, functional earthing and potential equalization	IEC 60601-1, Ed.3.1 EN 60601-1, Ed.3:2006 Cl.no.8.6	Upto 25 A 0.1 mΩ to 2.0 Ω
		Leakage currents and patient auxiliary currents (Preconditioning)	IEC 60601-1, Ed.3.1 EN 60601-1, Ed.3, Cl.no.5.7 IEC 60601-1, Ed.3.1 EN 60601-1, Ed.3 Cl.no.8.7	20° C to 30° C RH:93 % ±3 % 0.1 μA to 10.00 mA
		Dielectric strength (Preconditioning)	IEC 60601-1, Ed.3.1 EN 60601-1, Ed.3, Cl.no.5.7 IEC 60601-1, Ed.3.1 EN 60601-1, Ed.3, Cl.no.8.8.3	20° C to 30° C; RH:93 % ±3 % Qualitative 0.5 kV to 5 kV
		Mechanical strength and resistance to heat	IEC 60601-1, Ed.3.1 EN 60601-1, Ed.3, Cl.no.8.8.4.1	20°C to 250°C Upto 20 N

Sachin Tomar
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		Creepage distances and air clearances	IEC 60601-1, Ed.3.1 EN 60601-1, Ed.3 Cl.no.8.9	0.1 mm to 150 mm
		Instability – overbalance	IEC 60601-1, Ed.3.1 EN 60601-1, Ed.3 Cl.no.9.4.2	Up to 15 ⁰
		Instability from unwanted lateral movement	IEC 60601-1, Ed.3.1 EN 60601-1, Ed.3 Cl.no.9.4.3	Up to 15 ⁰ 1 N to 250 N
		Protection against excessive temperatures and other hazards	IEC 60601-1, Ed.3.1 EN 60601-1, Ed.3 Cl.no.11.1	20°C to 400°C
		Accuracy of controls and instruments and protection against hazardous Outputs	IEC 60601-1, Ed.3.1 EN 60601-1, Ed.3 Cl.no.12	Qualitative
		Push test	IEC 60601-1, Ed.3.1 EN 60601-1, Ed.3 Cl.no.15.3.2	250 N ± 10
		Impact test	IEC 60601-1, Ed.3.1 EN 60601-1, Ed.3 Cl.no.15.3.3	500 g ± 25 g
		Drop test: Hardwood board	IEC 60601-1, Ed.3.1 EN 60601-1, Ed.3 Cl. 15.3.4	Upto 50 mm thick
		Mould stress relief test	IEC 60601-1, Ed.3.1 EN 60601-1, Ed.3 Cl.no.15.3.6	20°C to 250° C
II.	EMC TEST FACILITY			
1.	EMI/EMC Test facility	Conducted Emission Test	CISPR 11,2015/EN55011 IEC/EN 60601-1-2 Cl.no.7	9 kHz to 30 MHz 10 dBµV to 120 dBµV

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		Harmonic Current Emission Test	IEC 61000-3-2,2014 IEC/EN 60601-1-2 Cl.no.7	Upto 40th Harmonics
		Electrostatic Discharge Immunity Test	IEC 61000-4-2 IEC/EN 60601-1-2, Cl.no.8	0.5 kV to 16 kV
		Electrical Fast Transient (EFT) / Burst Immunity Test	IEC 61000-4-4 IEC/EN 60601-1-2 Cl.no.8	Qualitative 0.5 kV to 5 kV
		Power Frequency Magnetic Field Immunity Test	IEC 61000-4-8 IEC/EN 60601-1-2 Cl.no.8	1 A/m to 100 A/m
		High Energy / Telecom Surge Immunity Test	IEC 61000-4-5 IEC/EN 60601-1-2 Cl.no. 8	0.5 kV to 5 kV
		Voltage dips, short interruptions and voltage variations immunity tests	IEC 61000-4-11 IEC/EN 60601-1-2,Cl.no.8	0%, 40%, 70%, 100%

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