Quality And Accreditation Institute

Centre for International Accreditation

(formerly Centre for Laboratory Accreditation)

Certificate of Accreditation

Astute Labs Private Limited

Sr. No. 82/1, Bajirao Dhawade Patil Industrial Estate, NDA Road,
Shivane, Pune-411023, Maharashtra, India

has been assessed and accredited in accordance with the Standard

ISO/IEC 17025:2017

"General Requirements for the Competence of Testing and Calibration Laboratories"
In the field of

Testing

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued compliance to the above standard & any other requirements specified by QAI.

QAI/CIA/TL/2024/0088

Valid from: ***26 November 2024***

Valid until: ***25 November 2026***

Dr. Bhupendra Kumar Rana
Chief Executive Officer

Prof. Vikram Kumar
Chair, CIA

User is advised to verify the current scope of accreditation by visiting our website: www.qai.org.in

Scope of Accreditation

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Accreditation Standard: ISO/IEC 17025:2017

Electronics Testing			
Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
1.	Medical electrical equipment	Burst immunity test	IEC 60601-1-2:2014 /AMD1:2020; IS 13450: Part 1: SEC 2: 2024
2.	Medical electrical equipment	Electrical fast transient (EFT)	IEC 60601-1-2:2014 /AMD1:2020; IS 13450: Part 1: SEC 2: 2024
3.	Medical electrical equipment	Conducted emission test	IEC 60601-1-2:2014 /AMD1:2020; IS 13450: Part 1: SEC 2: 2024
4.	Medical electrical equipment	Electrostatic discharge immunity test	IEC 60601-1-2:2014 /AMD1:2020; IS 13450: Part 1: SEC 2: 2024
5.	Medical electrical equipment	High energy / telecom Surge immunity test	IEC 60601-1-2:2014 /AMD1:2020; IS 13450: Part 1: SEC 2: 2024
6.	Medical electrical equipment	Harmonic current Emission test	IEC 60601-1-2:2014 /AMD1:2020; IS 13450: Part 1: SEC 2: 2024
7.	Medical electrical equipment	Power frequency Magnetic field Immunity test	IEC 60601-1-2:2014 /AMD1:2020; IS 13450: Part 1: SEC 2: 2024
8.	Medical electrical equipment	Voltage dips, short Interruptions and Voltage variations Immunity tests	IEC 60601-1-2:2014 /AMD1:2020; IS 13450: Part 1: SEC 2: 2024
9.	Medical electrical equipment	Cl. 4 general requirements	IEC 60601-1:2020; IS 13450: Part 1:2024

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
10.	Medical electrical equipment	Cl. 4.1 conditions for application to ME equipment or ME systems	IEC 60601-1:2020; IS 13450: Part 1:2024
11.	Medical electrical equipment	Cl. 4.2 risk management process for me equipment or ME systems	IEC 60601-1:2020; IS 13450: Part 1:2024
12.	Medical electrical equipment	Cl. 4.3 essential performance	IEC 60601-1:2020; IS 13450: Part 1:2024
13.	Medical electrical equipment	Cl. 4.4 expected service life	IEC 60601-1:2020; IS 13450: Part 1:2024
14.	Medical electrical equipment	Cl. 4.5 alternative risk control measures or test methods for ME equipment or ME systems	IEC 60601-1:2020; IS 13450: Part 1:2024
15.	Medical electrical equipment	Cl. 4.6 ME equipment or ME system parts that contact the patient	IEC 60601-1:2020; IS 13450: Part 1:2024
16.	Medical electrical equipment	Cl. 4.7 single fault condition for ME equipment	IEC 60601-1:2020; IS 13450: Part 1:2024
17.	Medical electrical equipment	Cl. 4.8 components of ME equipment	IEC 60601-1:2020; IS 13450: Part 1:2024

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
18.	Medical electrical equipment	Cl. 4.9 use of components with high-integrity characteristics in ME equipment	IEC 60601-1:2020; IS 13450: Part 1:2024
19.	Medical electrical equipment	Cl. 4.10 power supply	IEC 60601-1:2020; IS 13450: Part 1:2024
20.	Medical electrical equipment	Cl. 4.11 power input	IEC 60601-1:2020; IS 13450: Part 1:2024
21.	Medical electrical equipment	Cl. 5 general requirements for testing me equipment	IEC 60601-1:2020; IS 13450: Part 1:2024
22.	Medical electrical equipment	Cl. 5.1 type tests	IEC 60601-1:2020; IS 13450: Part 1:2024
23.	Medical electrical equipment	Cl. 5.2 number of samples	IEC 60601-1:2020; IS 13450: Part 1:2024
24.	Medical electrical equipment	Cl. 5.3 ambient temperature, humidity, atmospheric pressure	IEC 60601-1:2020; IS 13450: Part 1:2024
25.	Medical electrical equipment	Cl. 5.4 other conditions	IEC 60601-1:2020; IS 13450: Part 1:2024
26.	Medical electrical equipment	Cl. 5.5 supply voltages, type of current, nature of supply, frequency	IEC 60601-1:2020; IS 13450: Part 1:2024
27.	Medical electrical equipment	Cl. 5.6 repairs and modifications	IEC 60601-1:2020; IS 13450: Part 1:2024
28.	Medical electrical equipment	Cl. 5.7 humidity preconditioning treatment	IEC 60601-1:2020; IS 13450: Part 1:2024

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
29.	Medical electrical equipment	Cl. 5.8 sequence of tests	IEC 60601-1:2020; IS 13450: Part 1:2024
30.	Medical electrical equipment	Cl. 5.9 determination of applied parts and accessible parts	IEC 60601-1:2020; IS 13450: Part 1:2024
31.	Medical electrical equipment	Cl. 6 classification of ME equipment and ME systems	IEC 60601-1:2020; IS 13450: Part 1:2024
32.	Medical electrical equipment	Cl. 6.1 general	IEC 60601-1:2020; IS 13450: Part 1:2024
33.	Medical electrical equipment	Cl. 6.2 protection against electric shock	IEC 60601-1:2020; IS 13450: Part 1:2024
34.	Medical electrical equipment	Cl. 6.4 method(s) of sterilization	IEC 60601-1:2020; IS 13450: Part 1:2024
35.	Medical electrical equipment	Cl. 6.5 suitability for use in an oxygen rich environment	IEC 60601-1:2020; IS 13450: Part 1:2024
36.	Medical electrical equipment	Cl. 6.6 mode of operation	IEC 60601-1:2020; IS 13450: Part 1:2024
37.	Medical electrical equipment	Cl. 7 me equipment identification, marking and documents	IEC 60601-1:2020; IS 13450: Part 1:2024
38.	Medical electrical equipment	Cl. 7.1 general	IEC 60601-1:2020; IS 13450: Part 1:2024

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
39.	Medical electrical equipment	Cl. 7.2 marking on the outside of me equipment or ME	IEC 60601-1:2020; IS 13450: Part 1:2024
40.	Medical electrical equipment	Cl. 7.3 marking on the inside of ME equipment or ME equipment parts	IEC 60601-1:2020; IS 13450: Part 1:2024
41.	Medical electrical equipment	Cl. 7.4 marking of controls and instruments	IEC 60601-1:2020; IS 13450: Part 1:2024
42.	Medical electrical equipment	Cl. 7.5 safety signs	IEC 60601-1:2020; IS 13450: Part 1:2024
43.	Medical electrical equipment	Cl. 7.6 symbols	IEC 60601-1:2020; IS 13450: Part 1:2024
44.	Medical electrical equipment	Cl. 7.7 colours of the insulation of conductors	IEC 60601-1:2020; IS 13450: Part 1:2024
45.	Medical electrical equipment	Cl. 7.8 indicator lights and controls	IEC 60601-1:2020; IS 13450: Part 1:2024
46.	Medical electrical equipment	Cl. 7.9 accompanying documents	IEC 60601-1:2020; IS 13450: Part 1:2024
47.	Medical electrical equipment	Cl. 8 protection against electrical hazards from ME equipment	IEC 60601-1:2020; IS 13450: Part 1:2024
48.	Medical electrical equipment	Cl. 8.1 fundamental rule of protection against electric shock	IEC 60601-1:2020; IS 13450: Part 1:2024

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
49.	Medical electrical equipment	Cl. 8.2 requirements related to power sources	IEC 60601-1:2020; IS 13450: Part 1:2024
50.	Medical electrical equipment	Cl. 8.3 classification of applied parts	IEC 60601-1:2020; IS 13450: Part 1:2024
51.	Medical electrical equipment	Cl. 8.4 limitation of voltage, current or energy	IEC 60601-1:2020; IS 13450: Part 1:2024
52.	Medical electrical equipment	Cl. 8.5 separation of parts	IEC 60601-1:2020; IS 13450: Part 1:2024
53.	Medical electrical equipment	Cl. 8.6 protective earthing, functional earthing and potential equalization of ME equipment	IEC 60601-1:2020; IS 13450: Part 1:2024
54.	Medical electrical equipment	Cl. 8.7 leakage currents and patient auxiliary currents	IEC 60601-1:2020; IS 13450: Part 1:2024
55.	Medical electrical equipment	Cl. 8.8 insulation	IEC 60601-1:2020; IS 13450: Part 1:2024
56.	Medical electrical equipment	Cl. 8.9 creepage distances and air clearances	IEC 60601-1:2020; IS 13450: Part 1:2024
57.	Medical electrical equipment	Cl. 8.10 components and wiring	IEC 60601-1:2020; IS 13450: Part 1:2024
58.	Medical electrical equipment	Cl. 8.11 mains parts, components and layout	IEC 60601-1:2020; IS 13450: Part 1:2024

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
59.	Medical electrical equipment	Cl. 9 protection against mechanical hazards of ME equipment and ME systems	IEC 60601-1:2020; IS 13450: Part 1:2024
60.	Medical electrical equipment	Cl. 9.1 mechanical hazards of ME equipment	IEC 60601-1:2020; IS 13450: Part 1:2024
61.	Medical electrical equipment	Cl. 9.2 mechanical hazards associated with moving parts	IEC 60601-1:2020; IS 13450: Part 1:2024
62.	Medical electrical equipment	Cl. 9.3 mechanical hazard associated with surfaces, corners and edges	IEC 60601-1:2020; IS 13450: Part 1:2024
63.	Medical electrical equipment	Cl. 9.4 instability hazards	IEC 60601-1:2020; IS 13450: Part 1:2024
64.	Medical electrical equipment	Cl. 9.5 expelled parts hazard	IEC 60601-1:2020; IS 13450: Part 1:2024
65.	Medical electrical equipment	Cl. 9.6 acoustic energy (including infra- and ultrasound) and vibration	IEC 60601-1:2020; IS 13450: Part 1:2024
66.	Medical electrical equipment	Cl. 9.7 pressure vessels and parts subject to pneumatic and hydraulic pressure	IEC 60601-1:2020; IS 13450: Part 1:2024
67.	Medical electrical equipment	Cl. 9.8 mechanical hazards associated with support systems	IEC 60601-1:2020; IS 13450: Part 1:2024

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
68.	Medical electrical equipment	Cl. 10 protection against unwanted and excessive radiation hazards	IEC 60601-1:2020; IS 13450: Part 1:2024
69.	Medical electrical equipment	Cl. 10.2 alpha, beta, gamma, neutron and other particle radiation	IEC 60601-1:2020; IS 13450: Part 1:2024
70.	Medical electrical equipment	Cl. 10.3 microwave radiation	IEC 60601-1:2020; IS 13450: Part 1:2024
71.	Medical electrical equipment	Cl. 10.4 lasers	IEC 60601-1:2020; IS 13450: Part 1:2024
72.	Medical electrical equipment	Cl. 10.5 other visible electromagnetic radiation	IEC 60601-1:2020; IS 13450: Part 1:2024
73.	Medical electrical equipment	Cl. 10.6 infrared radiation	IEC 60601-1:2020; IS 13450: Part 1:2024
74.	Medical electrical equipment	Cl. 10.7 ultraviolet radiation	IEC 60601-1:2020; IS 13450: Part 1:2024
75.	Medical electrical equipment	Cl. 11 protection against excessive temperatures and other hazards	IEC 60601-1:2020; IS 13450: Part 1:2024
76.	Medical electrical equipment	Cl. 11.1 excessive temperatures in me equipment	IEC 60601-1:2020; IS 13450: Part 1:2024
77.	Medical electrical equipment	Cl. 11.2 fire prevention	IEC 60601-1:2020; IS 13450: Part 1:2024

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
78.	Medical electrical equipment	Cl. 11.3 constructional requirements for fire enclosures of ME equipment	IEC 60601-1:2020; IS 13450: Part 1:2024
79.	Medical electrical equipment	Cl. 11.4 ME equipment and ME systems intended for use with flammable anaesthetics	IEC 60601-1:2020; IS 13450: Part 1:2024
80.	Medical electrical equipment	Cl. 11.5 ME equipment and ME systems intended for use in conjunction with flammable agents	IEC 60601-1:2020; IS 13450: Part 1:2024
81.	Medical electrical equipment	Cl. 11.6 overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the me equipment	IEC 60601-1:2020; IS 13450: Part 1:2024
82.	Medical electrical equipment	Cl. 11.8 interruption of the power supply / supply mains to me equipment	IEC 60601-1:2020; IS 13450: Part 1:2024
83.	Medical electrical equipment	Cl. 12 accuracy of controls and instruments and protection against hazardous outputs	IEC 60601-1:2020; IS 13450: Part 1:2024

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Electronics Testing			
Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
84.	Medical electrical equipment	Cl. 13 hazardous situations and fault conditions for ME equipment	IEC 60601-1:2020; IS 13450: Part 1:2024
85.	Medical electrical equipment	Cl. 13.1 specific hazardous situations	IEC 60601-1:2020; IS 13450: Part 1:2024
86.	Medical electrical equipment	Cl. 13.2 single fault conditions	IEC 60601-1:2020; IS 13450: Part 1:2024
87.	Medical electrical equipment	Cl. 14 programmable electrical medical systems (PEMS)	IEC 60601-1:2020; IS 13450: Part 1:2024
88.	Medical electrical equipment	Cl. 15 construction of ME equipment	IEC 60601-1:2020; IS 13450: Part 1:2024
89.	Medical electrical equipment	Cl. 15.1 arrangements of controls and indicators of ME equipment	IEC 60601-1:2020; IS 13450: Part 1:2024
90.	Medical electrical equipment	Cl. 15.2 serviceability	IEC 60601-1:2020; IS 13450: Part 1:2024
91.	Medical electrical equipment	Cl. 15.3 mechanical strength	IEC 60601-1:2020; IS 13450: Part 1:2024
92.	Medical electrical equipment	Cl. 15.4 ME equipment components and general assembly	IEC 60601-1:2020; IS 13450: Part 1:2024

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Electronics Testing			
Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
93.	Medical electrical equipment	Cl. 15.5 mains supply transformers of me equipment and transformers providing separation in accordance with 8.5	IEC 60601-1:2020; IS 13450: Part 1:2024
94.	Medical electrical equipment	Cl. 16 ME systems	IEC 60601-1:2020; IS 13450: Part 1:2024
95.	Medical electrical equipment	Cl. 16.1 general requirements for the ME systems	IEC 60601-1:2020; IS 13450: Part 1:2024
96.	Medical electrical equipment	Cl. 16.2 accompanying documents of an ME system	IEC 60601-1:2020; IS 13450: Part 1:2024
97.	Medical electrical equipment	Cl. 16.3 power supply	IEC 60601-1:2020; IS 13450: Part 1:2024
98.	Medical electrical equipment	Cl. 16.4 enclosures	IEC 60601-1:2020; IS 13450: Part 1:2024
99.	Medical electrical equipment	Cl. 16.5 separation devices	IEC 60601-1:2020; IS 13450: Part 1:2024
100.	Medical electrical equipment	Cl. 16.6 leakage currents	IEC 60601-1:2020; IS 13450: Part 1:2024
101.	Medical electrical equipment	Cl. 16.7 protection against mechanical hazards	IEC 60601-1:2020; IS 13450: Part 1:2024
102.	Medical electrical equipment	Cl. 16.8 interruption of the power supply to parts of an ME system	IEC 60601-1:2020; IS 13450: Part 1:2024

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
103.	Medical electrical equipment	Cl. 16.9 ME system connections and wiring	IEC 60601-1:2020; IS 13450: Part 1:2024
104.	Infant phototherapy Equipment	Cl. 201.1 scope, object and related standards	IEC 60601-2-50:2020; IS 13450: Part 2: Sec 50:2022
105.	Infant phototherapy Equipment	Cl. 201.4 general requirements	IEC 60601-2-50:2020; IS 13450: Part 2: Sec 50:2022
106.	Infant phototherapy Equipment	Cl. 201.5 general requirements for testing ME equipment	IEC 60601-2-50:2020; IS 13450: Part 2: Sec 50:2022
107.	Infant phototherapy Equipment	Cl.201.6 classification of ME equipment and ME systems	IEC 60601-2-50:2020; IS 13450: Part 2: Sec 50:2022
108.	Infant phototherapy Equipment	Cl. 201.7 me equipment identification, marking and documents	IEC 60601-2-50:2020; IS 13450: Part 2: Sec 50:2022
109.	Infant phototherapy Equipment	Cl. 201.8 protection against electrical hazards from ME equipment	IEC 60601-2-50:2020; IS 13450: Part 2: Sec 50:2022
110.	Infant phototherapy Equipment	Cl. 201.9 protection against mechanical hazards of ME equipment and me systems	IEC 60601-2-50:2020; IS 13450: Part 2: Sec 50:2022

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
111.	Infant phototherapy Equipment	Cl. 201.10 protection against unwanted and excessive radiation hazards (excluding cl. No 10.1 and 10.4 as per IEC 60601-1/ IS 13450 part 1)	IEC 60601-2-50:2020; IS 13450: Part 2: Sec 50:2022
112.	Infant phototherapy Equipment	Cl. 201.11 protection against excessive temperatures and other hazards	IEC 60601-2-50:2020; IS 13450: Part 2: Sec 50:2022
113.	Infant phototherapy Equipment	Cl. 201.12 accuracy of controls and instruments and protection against hazardous outputs	IEC 60601-2-50:2020; IS 13450: Part 2: Sec 50:2022
114.	Infant phototherapy Equipment	Cl. 201.13 hazardous situations and fault conditions for ME equipment	IEC 60601-2-50:2020; IS 13450: Part 2: Sec 50:2022
115.	Infant phototherapy Equipment	Cl. 201.14 programmable electrical medical systems (PEMS)	IEC 60601-2-50:2020; IS 13450: Part 2: Sec 50:2022
116.	Infant phototherapy Equipment	Cl. 201.15 construction of ME equipment	IEC 60601-2-50:2020; IS 13450: Part 2: Sec 50:2022
117.	Infant phototherapy Equipment	Cl. 201.16 ME systems	IEC 60601-2-50:2020; IS 13450: Part 2: Sec 50:2022
118.	Multifunction patient monitors	Cl. 201.4 general requirements	IS/IEC 80601-2-49: 2018

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
119.	Multifunction patient monitors	Cl. 201.5 general requirements for testing ME equipment	IS/IEC 80601-2-49: 2018
120.	Multifunction patient monitors	Cl. 201.6 classification of ME equipment and ME systems	IS/IEC 80601-2-49: 2018
121.	Multifunction patient monitors	Cl. 201.7 ME equipment identification, marking and documents	IS/IEC 80601-2-49: 2018
122.	Multifunction patient monitors	Cl. 201.8 protection against electrical hazards from ME equipment	IS/IEC 80601-2-49: 2018
123.	Multifunction patient monitors	Cl. 201.9 protection against mechanical hazards of ME equipment and ME systems	IS/IEC 80601-2-49: 2018
124.	Multifunction patient monitors	Cl. 201.10 protection against unwanted and excessive radiation hazards (excluding cl. No 10.1 and 10.4 as per IEC 60601-1/ IS 13450 part 1)	IS/IEC 80601-2-49: 2018
125.	Multifunction patient monitors	Cl. 201.11 protection against excessive temperatures and other hazards	IS/IEC 80601-2-49: 2018

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
126.	Multifunction patient monitors	Cl. 201.12 accuracy of controls and instruments and protection against hazardous outputs	IS/IEC 80601-2-49: 2018
127.	Multifunction patient monitors	Cl. 201.13 hazardous situations and fault conditions for ME equipment	IS/IEC 80601-2-49: 2018
128.	Multifunction patient monitors	Cl. 201.14 programmable electrical medical systems (PEMS)	IS/IEC 80601-2-49: 2018
129.	Multifunction patient monitors	Cl. 201.15 construction of ME equipment	IS/IEC 80601-2-49: 2018
130.	Multifunction patient monitors	Cl. 201.16 ME systems	IS/IEC 80601-2-49: 2018
131.	Multifunction patient monitors	Cl. 208 general requirements, tests and guidance for alarm systems in medical Electrical equipment and medical electrical systems	IS/IEC 80601-2-49: 2018
132.	Invasive blood pressure monitoring Equipment	Cl. 201.1 scope, object and related standards	IEC 60601-2-34: 2011 IS 13450: Part 2: Sec 34: 2019

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	Medical Electrical Equipment		
133.	Invasive blood pressure monitoring equipment	Cl. 201.4 general requirements	IEC 60601-2-34: 2011 IS 13450: Part 2: Sec 34: 2019
134.	Invasive blood pressure monitoring equipment	Cl. 201.5 general requirements for testing of ME equipment	IEC 60601-2-34: 2011 IS 13450: Part 2: Sec 34: 2019
135.	Invasive blood pressure monitoring equipment	Cl. 201.6 classification of ME equipment and ME systems	IEC 60601-2-34: 2011 IS 13450: Part 2: Sec 34: 2019
136.	Invasive blood pressure monitoring equipment	Cl. 201.6.2 Protection against electric shock	IEC 60601-2-34: 2011 IS 13450: Part 2: Sec 34: 2019
137.	Invasive blood pressure monitoring equipment	Cl. 201.6.6 Mode of operation	IEC 60601-2-34: 2011 IS 13450: Part 2: Sec 34: 2019
138.	Invasive blood pressure monitoring equipment	Cl. 201.7 ME equipment identification, marking and documents	IEC 60601-2-34: 2011 IS 13450: Part 2: Sec 34: 2019
139.	Invasive blood pressure monitoring equipment	Cl. 201.8 protection against electrical hazards from ME equipment	IEC 60601-2-34: 2011 IS 13450: Part 2: Sec 34: 2019
140.	Invasive blood pressure monitoring equipment	Cl. 201.9 protection against mechanical hazards of ME equipment and ME systems	IEC 60601-2-34: 2011 IS 13450: Part 2: Sec 34: 2019

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Electronics Testing			
Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
141.	Invasive blood pressure monitoring equipment	Cl.201.10 protection against unwanted and excessive radiation hazards (excluding cl. No 10.1 and 10.4 as per IEC 60601-1/ IS 13450 part 1)	IEC 60601-2-34: 2011 IS 13450: Part 2: Sec 34: 2019
142.	Invasive blood pressure monitoring equipment	Cl.201.11 protection against excessive temperatures and other hazards	IEC 60601-2-34: 2011 IS 13450: Part 2: Sec 34: 2019
143.	Invasive blood pressure monitoring equipment	Cl. 201.12 accuracy of controls and instruments and protection against hazardous outputs	IEC 60601-2-34: 2011 IS 13450: Part 2: Sec 34: 2019
144.	Invasive blood pressure monitoring equipment	Cl. 201.13 hazardous situations and fault conditions	IEC 60601-2-34: 2011 IS 13450: Part 2: Sec 34: 2019
145.	Invasive blood pressure monitoring equipment	Cl. 201.14 programmable electrical medical systems (PEMS)	IEC 60601-2-34: 2011 IS 13450: Part 2: Sec 34: 2019
146.	Invasive blood pressure monitoring equipment	Cl. 201.15 construction of ME equipment	IEC 60601-2-34: 2011 IS 13450: Part 2: Sec 34: 2019
147.	Invasive blood pressure monitoring equipment	Cl. 201.16 ME systems	IEC 60601-2-34: 2011 IS 13450: Part 2: Sec 34: 2019

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
148.	Invasive blood pressure monitoring equipment	Cl. 208 general requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	IEC 60601-2-34: 2011 IS 13450: Part 2: Sec 34: 2019
149.	Electrocardiographic monitoring equipment	Cl. 201.1 Scope, object and related standards	IEC 60601-2-27: 2011 IS 13450: Part 2: Sec 27: 2018
150.	Electrocardiographic monitoring equipment	Cl. 201.4 General requirements	IEC 60601-2-27: 2011 IS 13450: Part 2: Sec 27: 2018
151.	Electrocardiographic monitoring equipment	Cl. 201.5 General requirements for testing of ME equipment	IEC 60601-2-27: 2011 IS 13450: Part 2: Sec 27: 2018
152.	Electrocardiographic monitoring equipment	Cl. 201.6 classification of me equipment and ME systems	IEC 60601-2-27: 2011 IS 13450: Part 2: Sec 27: 2018
153.	Electrocardiographic monitoring equipment	Cl. 201.7 Me equipment identification, marking and documents	IEC 60601-2-27: 2011 IS 13450: Part 2: Sec 27: 2018
154.	Electrocardiographic monitoring equipment	Cl. 201.8 protection against electrical hazards from ME equipment	IEC 60601-2-27: 2011 IS 13450: Part 2: Sec 27: 2018
155.	Electrocardiographic monitoring equipment	Cl. 201.9 protection against mechanical hazards of ME equipment and ME systems	IEC 60601-2-27: 2011 IS 13450: Part 2: Sec 27: 2018

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
156.	Electrocardiographic monitoring equipment	Cl. 201.10 protection against unwanted and excessive radiation hazards (excluding cl. No 10.1 and 10.4 as per IEC 60601-1/ IS 13450 part 1)	IEC 60601-2-27: 2011 IS 13450: Part 2: Sec 27: 2018
157.	Electrocardiographic monitoring equipment	Cl. 201.11 protection against excessive temperatures and other hazards	IEC 60601-2-27: 2011 IS 13450: Part 2: Sec 27: 2018
158.	Electrocardiographic monitoring equipment	Cl. 201.12 Accuracy of controls and instruments and protection against hazardous outputs	IEC 60601-2-27: 2011 IS 13450: Part 2: Sec 27: 2018
159.	Electrocardiographic monitoring equipment	Cl. 201.13 hazardous situations and fault conditions	IEC 60601-2-27: 2011 IS 13450: Part 2: Sec 27: 2018
160.	Electrocardiographic monitoring equipment	Cl. 201.14 programmable electrical medical systems (PEMS)	IEC 60601-2-27: 2011 IS 13450: Part 2: Sec 27: 2018
161.	Electrocardiographic monitoring equipment	Cl. 201.15 construction of me equipment	IEC 60601-2-27: 2011 IS 13450: Part 2: Sec 27: 2018
162.	Electrocardiographic monitoring equipment	Cl. 201.16 ME systems	IEC 60601-2-27: 2011 IS 13450: Part 2: Sec 27: 2018

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Electronics Testing			
Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
163.	Electrocardiographic monitoring equipment	Cl. 208 general requirements, tests and guidance for alarm systems in medical Electrical equipment and medical electrical systems	IEC 60601-2-27: 2011 IS 13450: Part 2: Sec 27: 2018
164.	Electrocardiographs	Cl. 201.1 scope, object and related standards	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
165.	Electrocardiographs	Cl. 201.4 General requirements	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
166.	Electrocardiographs	Cl. 201.5 General requirements for testing of ME equipment	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
167.	Electrocardiographs	Cl. 201.6 classification of ME equipment and ME systems	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
168.	Electrocardiographs	Cl. 201.7 ME equipment identification, marking and documents	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
169.	Electrocardiographs	Cl. 201.7.4.101 patient cable and patient cable to ME equipment connector	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
170.	Electrocardiographs	Cl. 201.8 protection against electrical hazards from ME equipment	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018

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Electronics Testing			
Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
171.	Electrocardiographs	Cl. 201.8.5.5.1 Defibrillation protection	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
172.	Electrocardiographs	Cl. 201.8.5.5.2 energy reduction test	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
173.	Electrocardiographs	Cl. 201.9 protection against mechanical hazards of ME equipment and ME systems	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
174.	Electrocardiographs	Cl. 201.10 protection against unwanted and excessive radiation hazards (excluding cl. No 10.1 and 10.4 as per IEC 60601-1/ IS 13450 part 1)	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
175.	Electrocardiographs	Cl. 201.11 protection against excessive temperatures and other hazards	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
176.	Electrocardiographs	Cl. 201.12 accuracy of controls and instruments and protection against hazardous outputs	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
177.	Electrocardiographs	Cl. 201.12.1.101.1 automated measurements on ECGs	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
178.	Electrocardiographs	Cl. 201.12.1.101.2 requirements for amplitude measurements	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
179.	Electrocardiographs	Cl. 201.12.1.101.3 requirements for interval measurements	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
180.	Electrocardiographs	Cl. 201.12.1.101.3.1 requirements for absolute interval and wave duration measurements	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
181.	Electrocardiographs	Cl. 201.12.1.101.3.2 requirements for interval measurements on biological	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
182.	Electrocardiographs	Cl. 201.12.4 protection against hazardous output	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
183.	Electrocardiographs	Cl. 201.12.4.101 indication of inoperable electrocardiograph	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
184.	Electrocardiographs	Cl.201.12.4.102 leads	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
185.	Electrocardiographs	Cl. 201.12.4.102.1 lead representation, nomenclature and definition	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
186.	Electrocardiographs	Cl. 201.12.4.102.2 minimum required configuration	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
187.	Electrocardiographs	Cl. 201.12.4.102.3 test of lead networks	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
188.	Electrocardiographs	Cl. 201.12.4.102.3.1 general	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
189.	Electrocardiographs	Cl. 201.12.4.102.3.2 goldberger and wilson leads	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
190.	Electrocardiographs	Cl. 201.12.4.102.4 recovery time	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
191.	Electrocardiographs	Cl. 201.12.4.103 input impedance	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
192.	Electrocardiographs	Cl. 201.12.4.104 required gains	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
193.	Electrocardiographs	Cl. 201.12.4.105 Reduction of the effects of unwanted external voltages	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
194.	Electrocardiographs	Cl. 201.12.4.105.1 common mode rejection	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
195.	Electrocardiographs	Cl. 201.12.4.105.2 overload tolerance	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
196.	Electrocardiographs	Cl. 201.12.4.105.3 filters (including line frequency interference filters)	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
197.	Electrocardiographs	Cl. 201.12.4.106 baseline	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
198.	Electrocardiographs	Cl. 201.12.4.106.1 noise level	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
199.	Electrocardiographs	Cl. 201.12.4.106.2 channel crosstalk	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
200.	Electrocardiographs	Cl. 201.12.4.107 distortion	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
201.	Electrocardiographs	Cl. 201.12.4.107.1.1.1 high frequency response	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
202.	Electrocardiographs	Cl. 201.12.4.107.1.1.2 low frequency (impulse) response	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
203.	Electrocardiographs	Cl. 201.12.4.107.1.2 test with calibration ECGs	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
204.	Electrocardiographs	Cl. 201.12.4.107.2 linearity and dynamic range	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
205.	Electrocardiographs	Cl. 201.12.4.107.3 sampling and amplitude quantisation during data acquisition	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
206.	Electrocardiographs	Cl. 201.12.4.108 printing, electronic storage and transmission	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
207.	Electrocardiographs	Cl. 201.12.4.108.1 record identification	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
208.	Electrocardiographs	Cl. 201.12.4.108.2 patient identification	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
209.	Electrocardiographs	Cl. 201.12.4.108.3 ECG reporting on paper	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
210.	Electrocardiographs	Cl. 201.12.4.108.3.1 time and event markers	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
211.	Electrocardiographs	Cl. 201.12.4.108.3.2 recording speed	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
212.	Electrocardiographs	Cl. 201.12.4.108.3.3 time and amplitude ruling	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
213.	Electrocardiographs	Cl. 201.12.4.109 use with cardiac pacemakers	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
214.	Electrocardiographs	Cl. 201.13 hazardous situations and fault conditions	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
215.	Electrocardiographs	Cl. 201.14 programmable electrical medical systems (PEMS)	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
216.	Electrocardiographs	Cl. 201.15 construction of ME equipment	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018
217.	Electrocardiographs	Cl. 201.16 ME systems	IEC 60601-2-25: 2011 IS 13450: Part 2: Sec 25: 2018

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
218.	Infusion pumps and controllers	Cl. 201.1 Scope, object and related standards	IEC 60601-2-24: 2012 IS 13450: Part 2: Sec 24: 2019
219.	Infusion pumps and controllers	Cl. 201.4 General requirements	IEC 60601-2-24: 2012 IS 13450: Part 2: Sec 24: 2019
220.	Infusion pumps and controllers	Cl. 201.5 general requirements for testing of ME equipment	IEC 60601-2-24: 2012 IS 13450: Part 2: Sec 24: 2019
221.	Infusion pumps and controllers	Cl. 201.6 classification of me equipment and ME systems	IEC 60601-2-24: 2012 IS 13450: Part 2: Sec 24: 2019
222.	Infusion pumps and controllers	Cl. 201.7 ME equipment identification, marking and documents	IEC 60601-2-24: 2012 IS 13450: Part 2: Sec 24: 2019
223.	Infusion pumps and controllers	Cl. 201.8 protection against electrical hazards from ME equipment	IEC 60601-2-24: 2012 IS 13450: Part 2: Sec 24: 2019
224.	Infusion pumps and controllers	Cl. 201.9 protection against mechanical hazards of me equipment and ME systems	IEC 60601-2-24: 2012 IS 13450: Part 2: Sec 24: 2019
225.	Infusion pumps and controllers	Cl. 201.10 protection against unwanted and excessive radiation hazards (excluding cl. No 10.1 and 10.4 as per IEC 60601-1/ IS 13450 part 1)	IEC 60601-2-24: 2012 IS 13450: Part 2: Sec 24: 2019

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
226.	Infusion pumps and controllers	Cl. 201.11 protection against excessive temperatures and other hazards	IEC 60601-2-24: 2012 IS 13450: Part 2: Sec 24: 2019
227.	Infusion pumps and controllers	Cl. 201.12 accuracy of controls and instruments and protection against hazardous outputs	IEC 60601-2-24: 2012 IS 13450: Part 2: Sec 24: 2019
228.	Infusion pumps and controllers	Cl. 201.13 hazardous situations and fault conditions	IEC 60601-2-24: 2012 IS 13450: Part 2: Sec 24: 2019
229.	Infusion pumps and controllers	Cl. 201.14 programmable electrical medical systems (PEMS)	IEC 60601-2-24: 2012 IS 13450: Part 2: Sec 24: 2019
230.	Infusion pumps and controllers	Cl. 201.15 construction of ME equipment	IEC 60601-2-24: 2012 IS 13450: Part 2: Sec 24: 2019
231.	Infusion pumps and controllers	Cl. 201.16 ME systems	IEC 60601-2-24: 2012 IS 13450: Part 2: Sec 24: 2019
232.	Infusion pumps and controllers	Cl. 206 usability	IEC 60601-2-24: 2012 IS 13450: Part 2: Sec 24: 2019
233.	Infusion pumps and controllers	Cl. 208 general requirements, tests and guidance for alarm systems in medical	IEC 60601-2-24: 2012 IS 13450: Part 2: Sec 24: 2019
234.	Anaesthetic workstation	Cl. 201.4 General requirements	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024

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	Medical Electrical Equipment		
235.	Anaesthetic workstation	Cl. 201.5 general requirements for testing ME equipment	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024 ISO 80601-2-13
236.	Anaesthetic workstation	Cl. 201.6 classification of ME equipment or ME systems	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024 ISO 80601-2-13
237.	Anaesthetic workstation	Cl. 201.7 ME equipment identification, marking and documents	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024 ISO 80601-2-13
238.	Anaesthetic workstation	Cl. 201.8 protection against electrical hazards from ME equipment	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024 ISO 80601-2-13
239.	Anaesthetic workstation	Cl. 201.9 protection against mechanical hazards of ME equipment and ME systems	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024 ISO 80601-2-13
240.	Anaesthetic workstation	Cl. 201.10 protection against unwanted and excessive radiation hazards (excluding cl. No 10.1 and 10.4 as per IEC 60601-1/ IS 13450 part 1)	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024 ISO 80601-2-13
241.	Anaesthetic workstation	Cl. 201.11 protection against excessive temperatures and other hazards	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024 ISO 80601-2-13

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
242.	Anaesthetic workstation	Cl. 201.12 accuracy of controls and instruments and protection against hazardous outputs	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024 ISO 80601-2-13
243.	Anaesthetic workstation	Cl. 201.13 Hazardous situations and fault conditions	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024 ISO 80601-2-13
244.	Anaesthetic workstation	Cl. 201.14 programmable electrical medical systems (PEMS)	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024 ISO 80601-2-13
245.	Anaesthetic workstation	Cl. 201.15 Construction of ME equipment	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024
246.	Anaesthetic workstation	Cl.201.16 ME systems	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024
247.	Anaesthetic workstation	Cl. 201.101 additional requirements for anaesthetic gas delivery systems	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024 ISO 80601-2-13
248.	Anaesthetic workstation	Cl. 201.102 additional requirements for an anaesthetic breathing system	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024 ISO 80601-2-13
249.	Anaesthetic workstation	Cl. 201.103 additional requirements for an AGSS	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024 ISO 80601-2-13

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	Medical Electrical Equipment		
250.	Anaesthetic workstation	Cl. 201.104 additional requirements for interchangeable and non-interchangeable Anaesthetic vapour delivery systems	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024 ISO 80601-2-13
251.	Anaesthetic workstation	201.105 additional requirements for an anaesthetic ventilator	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024 ISO 806 01-2-13
252.	Anaesthetic workstation	Cl. 201.106 display of pressure-volume loops	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024
253.	Anaesthetic workstation	Cl. 201.107 clinical evaluation	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024
254.	Anaesthetic workstation	Cl. 206 usability	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024
255.	Anaesthetic workstation	Cl. 208 general requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024 ISO 80601-2-13
256.	Anaesthetic workstation	Cl. 209 requirements for environmentally conscious design	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024 ISO 80601-2-13

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	Medical Electrical Equipment		
257.	Anaesthetic workstation	Cl. 210 process requirements for the development of physiologic closed-loop Controllers	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024 ISO 80601-2-13
258.	Anaesthetic workstation	Cl. 211 requirements for medical electrical equipment and medical electrical Systems used in the home health care environment	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024 ISO 80601-2-13
259.	Anaesthetic workstation	Cl. 212 requirements for medical electrical equipment and medical electrical systems Intended for use in the emergency medical services environment	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024 ISO 80601-2-13
260.	Anaesthetic workstation	Cl. Bb.2 spark ignition tests	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024
261.	Anaesthetic workstation	Cl. Bb.3 surface temperature ignition tests	IEC 60601-2-13 2009 IS 13450: Part 2: Sec 13: 2024
262.	Critical care ventilators	Cl. 201.4 general requirements	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020
263.	Critical care ventilators	Cl. 201.5 general requirements for testing of ME equipment	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020

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Electronics Testing			
Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
264.	Critical care ventilators	Cl. 201.6 classification of ME equipment and ME systems	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020
265.	Critical care ventilators	Cl. 201.7 ME equipment identification, marking and documents	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020
266.	Critical care ventilators	Cl. 201.8 protection against electrical hazards from ME equipment	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020
267.	Critical care ventilators	Cl. 201.9 protection against mechanical hazards of ME equipment and ME systems	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020
268.	Critical care ventilators	Cl. 201.10 protection against unwanted and excessive radiation hazards (excluding cl 10.1 & 10.4 of IEC 60601-1/ IS 13450-1)	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020
269.	Critical care ventilators	Cl. 201.11 protection against excessive temperatures and other hazards	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
270.	Critical care ventilators	Cl. 201.12 accuracy of controls and instruments and protection against hazardous outputs	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020
271.	Critical care ventilators	Cl. 201.13 hazardous situations and fault conditions for ME equipment	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020
272.	Critical care ventilators	Cl. 201.14 programmable electrical medical systems (PEMS)	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020
273.	Critical care ventilators	Cl. 201.15 construction of ME equipment	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020
274.	Critical care ventilators	Cl. 201.16 ME systems	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020
275.	Critical care ventilators	Cl. 201.101 Gas connections	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020
276.	Critical care ventilators	Cl. 201.102 Requirements for the VBS and accessories	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020
277.	Critical care ventilators	Cl. 201.103 Spontaneous breathing during loss of power supply	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020

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Electronics Testing			
Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
278.	Critical care ventilators	Cl. 201.104 Indication of duration of operation	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020
279.	Critical care ventilators	Cl. 201.105 Functional connection	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020
280.	Critical care ventilators	Cl. 201.106 display loops	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020
281.	Critical care ventilators	Cl. 201.107 Timed ventilatory pause	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020
282.	Critical care ventilators	Cl. 206 Usability	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020
283.	Critical care ventilators	Cl. 208 general requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	IS 13450: Part 2: Sec 12:2023 ISO 80601-2-12: 2020
284.	Cardiac defibrillators	Cl. 201 .4 General requirements	IEC 60601-2-4: 2010 IS 13450: Part 2: Sec 4: 2018
285.	Cardiac defibrillators	Cl. 201 .5 General requirements for testing of ME equipment	IEC 60601-2-4: 2010 IS 13450: Part 2: Sec 4: 2018

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
286.	Cardiac defibrillators	Cl. 201 .6 classification of ME equipment and ME systems	IEC 60601-2-4: 2010 IS 13450: Part 2: Sec 4: 2018
287.	Cardiac defibrillators	Cl. 201 .7 ME equipment identification, marking and documents	IEC 60601-2-4: 2010 IS 13450: Part 2: Sec 4: 2018
288.	Cardiac defibrillators	Cl. 201 .8 protection against electrical hazards from ME equipment	IEC 60601-2-4: 2010 IS 13450: Part 2: Sec 4: 2018
289.	Cardiac defibrillators	Cl. 201 .9 protection against mechanical hazards of ME equipment and ME systems	IEC 60601-2-4: 2010 IS 13450: Part 2: Sec 4: 2018
290.	Cardiac defibrillators	Cl. 201.10 protection against unwanted and excessive radiation hazards (excluding cl 10.1 & 10.4 OF IEC 60601-1/ IS 13450-1)	IEC 60601-2-4: 2010 IS 13450: Part 2: Sec 4: 2018
291.	Cardiac defibrillators	Cl. 201.11 protection against excessive temperatures and other hazards	IEC 60601-2-4: 2010 IS 13450: Part 2: Sec 4: 2018
292.	Cardiac defibrillators	Cl. 201.12 accuracy of controls and instruments and protection against hazardous outputs	IEC 60601-2-4: 2010 IS 13450: Part 2: Sec 4: 2018

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
293.	Cardiac defibrillators	Cl. 201.13 hazardous situations and fault conditions	IEC 60601-2-4: 2010 IS 13450: Part 2: Sec 4: 2018
294.	Cardiac defibrillators	Cl. 201.14 programmable electrical medical systems (PEMS)	IEC 60601-2-4: 2010 IS 13450: Part 2: Sec 4: 2018
295.	Cardiac defibrillators	Cl. 201.15 construction of ME equipment	IEC 60601-2-4: 2010 IS 13450: Part 2: Sec 4: 2018
296.	Cardiac defibrillators	Cl. 201.16 ME systems	IEC 60601-2-4: 2010 IS 13450: Part 2: Sec 4: 2018
297.	High frequency surgical equipment and high frequency surgical accessories	Cl. 201.4 general requirements	IEC 60601-2-2: 2023, IS 13450: Part 2: Sec 2: 2024
298.	High frequency surgical equipment and high frequency surgical accessories	Cl. 201.5 general requirements for testing of ME equipment	IEC 60601-2-2: 2023, IS 13450: Part 2: Sec 2: 2024
299.	High frequency surgical equipment and high frequency surgical accessories	Cl. 201.6 classification of ME equipment and ME systems	IEC 60601-2-2: 2023, IS 13450: Part 2: Sec 2: 2024
300.	High frequency surgical equipment and high frequency surgical accessories	Cl. 201.7 ME equipment identification, marking and documents	IEC 60601-2-2: 2023, IS 13450: Part 2: Sec 2: 2024

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Electronics Testing			
Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
301.	High frequency surgical equipment and high frequency surgical accessories	Cl. 201.8 protection against electrical hazards from ME equipment	IEC 60601-2-2: 2023, IS 13450: Part 2: Sec 2: 2024
302.	High frequency surgical equipment and high frequency surgical accessories	Cl.201.9 protection against mechanical hazards of ME equipment and ME systems	IEC 60601-2-2: 2023, IS 13450: Part 2: Sec 2: 2024
303.	High frequency surgical equipment and high frequency surgical accessories	Cl. 201.10 protection against unwanted and excessive radiation hazard (excluding cl 10.1 & 10.4 of IEC 60601-1/ IS 13450-1)	IEC 60601-2-2: 2023, IS 13450: Part 2: Sec 2: 2024
304.	High frequency surgical equipment and high frequency surgical accessories	Cl. 201.11 protection against excessive temperatures and other hazards	IEC 60601-2-2: 2023, IS 13450: Part 2: Sec 2: 2024
305.	High frequency surgical equipment and high frequency surgical accessories	Cl. 201.12 accuracy of controls and instruments and protection against hazardous outputs	IEC 60601-2-2: 2023, IS 13450: Part 2: Sec 2: 2024
306.	High frequency surgical equipment and high frequency surgical accessories	Cl. 201.13 hazardous situations and fault conditions for ME equipment	IEC 60601-2-2: 2023, IS 13450: Part 2: Sec 2: 2024
307.	High frequency surgical equipment and high frequency surgical accessories	Cl. 201.14 programmable electrical medical systems (PEMS)	IEC 60601-2-2: 2023, IS 13450: Part 2: Sec 2: 2024

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Electronics Testing			
Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
308.	High frequency surgical equipment and high frequency surgical accessories	Cl. 201.15 construction of ME equipment	IEC 60601-2-2: 2023, IS 13450: Part 2: Sec 2: 2024
309.	High frequency surgical equipment and high frequency surgical accessories	Cl. 201.16 ME systems	IEC 60601-2-2: 2023, IS 13450: Part 2: Sec 2: 2024
310.	High frequency surgical equipment and high frequency surgical accessories	Cl. 208 general requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	IEC 60601-2-2: 2023, IS 13450: Part 2: Sec 2: 2024
311.	Infant incubators	Cl. 201 .4 general requirements	IEC 60601-2-19: 2020 IS 13450: Part 2: Sec 19: 2023
312.	Infant incubators	Cl. 201.5 general requirements for testing ME equipment	IEC 60601-2-19: 2020 IS 13450: Part 2: Sec 19: 2023
313.	Infant incubators	Cl. 201.6 classification of ME equipment and me systems	IEC 60601-2-19: 2020 IS 13450: Part 2: Sec 19: 2023
314.	Infant incubators	Cl. 201.7 ME equipment identification, marking and documents	IEC 60601-2-19: 2020 IS 13450: Part 2: Sec 19: 2023

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
315.	Infant incubators	Cl. 201.8 protection against electrical hazards from ME equipment	IEC 60601-2-19: 2020 IS 13450: Part 2: Sec 19: 2023
316.	Infant incubators	Cl. 201.9 protection against mechanical hazards of ME equipment and me systems	IEC 60601-2-19: 2020 IS 13450: Part 2: Sec 19: 2023
317.	Infant incubators	Cl. 201.10 protection against unwanted and excessive radiation hazards (excluding cl 10.1 & 10.4 OF IEC 60601-1/ IS 13450-1)	IEC 60601-2-19: 2020 IS 13450: Part 2: Sec 19: 2023
318.	Infant incubators	Cl. 201.11 protection against excessive temperatures and other hazards	IEC 60601-2-19: 2020 IS 13450: Part 2: Sec 19: 2023
319.	Infant incubators	Cl. 201.12 accuracy of controls and instruments and protection against Hazardous outputs	IEC 60601-2-19: 2020 IS 13450: Part 2: Sec 19: 2023
320.	Infant incubators	Cl. 201.13 hazardous situations and fault conditions	IEC 60601-2-19: 2020 IS 13450: Part 2: Sec 19: 2023
321.	Infant incubators	Cl. 201.14 programmable electrical medical systems (PEMS)	IEC 60601-2-19: 2020 IS 13450: Part 2: Sec 19: 2023

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
322.	Infant incubators	Cl. 201.15 construction of ME equipment	IEC 60601-2-19: 2020 IS 13450: Part 2: Sec 19: 2023
323.	Infant incubators	Cl. 201.16 ME systems	IEC 60601-2-19: 2020 IS 13450: Part 2: Sec 19: 2023
324.	Infant radiant warmers	Cl. 201 .4 general requirements	IEC 60601-2-21: 2020 IS 13450: Part 2: Sec 21: 2023
325.	Infant radiant warmers	Cl. 201.5 general requirements for testing of ME equipment	IEC 60601-2-21: 2020 IS 13450: Part 2: Sec 21: 2023
326.	Infant radiant warmers	Cl. 201 .6 classification of ME equipment and ME systems	IEC 60601-2-21: 2020 IS 13450: Part 2: Sec 21: 2023
327.	Infant radiant warmers	Cl. 201 .7 ME equipment identification, marking and documents	IEC 60601-2-21: 2020 IS 13450: Part 2: Sec 21: 2023
328.	Infant radiant warmers	Cl. 201.8 protection against electrical hazards from ME equipment	IEC 60601-2-21: 2020 IS 13450: Part 2: Sec 21: 2023
329.	Infant radiant warmers	Cl. 201.9 protection against mechanical hazards of ME equipment and ME systems	IEC 60601-2-21: 2020 IS 13450: Part 2: Sec 21: 2023

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
330.	Infant radiant warmers	Cl. 201.10 protection against unwanted and excessive radiation hazards (excluding cl 10.1 & 10.4 OF IEC 60601-1/ IS 13450-1)	IEC 60601-2-21: 2020 IS 13450: Part 2: Sec 21: 2023
331.	Infant radiant warmers	Cl. 201 .11 protection against excessive temperatures and other hazards	IEC 60601-2-21: 2020 IS 13450: Part 2: Sec 21: 2023
332.	Infant radiant warmers	Cl. 201.12 accuracy of controls and instruments and protection against	IEC 60601-2-21: 2020 IS 13450: Part 2: Sec 21: 2023
333.	Infant radiant warmers	Cl. 201.13 hazardous situations and fault conditions	IEC 60601-2-21: 2020 IS 13450: Part 2: Sec 21: 2023
334.	Infant radiant warmers	Cl. 201.14 programmable electrical medical systems (PEMS)	IEC 60601-2-21: 2020 IS 13450: Part 2: Sec 21: 2023
335.	Infant radiant warmers	Cl. 201.15 construction of ME equipment	IEC 60601-2-21: 2020 IS 13450: Part 2: Sec 21: 2023
336.	Infant radiant warmers	Cl. 201.16 ME systems	IEC 60601-2-21: 2020 IS 13450: Part 2: Sec 21: 2023
337.	Endoscopic equipment	Cl. 201.1 scope, object and related standards	IEC 60601-2-18: 2009 IS 13450: Part 2: Sec 18: 2014
338.	Endoscopic equipment	Cl. 201.4 general requirements	IEC 60601-2-18: 2009 IS 13450: Part 2: Sec 18: 2014

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
339.	Endoscopic equipment	Cl. 201.5 general requirements for testing of ME equipment	IEC 60601-2-18: 2009 IS 13450: Part 2: Sec 18: 2014
340.	Endoscopic equipment	Cl. 201.6 classification of ME equipment and me systems	IEC 60601-2-18: 2009 IS 13450: Part 2: Sec 18: 2014
341.	Endoscopic equipment	Cl. 201.7 ME equipment identification, marking and documents	IEC 60601-2-18: 2009 IS 13450: Part 2: Sec 18: 2014
342.	Endoscopic equipment	Cl. 201.8 protection against electrical hazards from ME equipment	IEC 60601-2-18: 2009 IS 13450: Part 2: Sec 18: 2014
343.	Endoscopic equipment	Cl. 201.9 protection against mechanical hazards of ME equipment and me systems	IEC 60601-2-18: 2009 IS 13450: Part 2: Sec 18: 2014
344.	Endoscopic equipment	Cl. 201.10 protection against unwanted and excessive radiation hazards (excluding cl 10.1 & 10.4 of IEC 60601-1/ IS 13450-1)	IEC 60601-2-18: 2009 IS 13450: Part 2: Sec 18: 2014
345.	Endoscopic equipment	Cl. 201.11 protection against excessive temperatures and other hazards	IEC 60601-2-18: 2009 IS 13450: Part 2: Sec 18: 2014

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
346.	Endoscopic equipment	Cl. 201.12 accuracy of controls and instruments and protection against hazardous outputs	IEC 60601-2-18: 2009 IS 13450: Part 2: Sec 18: 2014
347.	Endoscopic equipment	Cl. 201.13 hazardous situations and fault conditions	IEC 60601-2-18: 2009 IS 13450: Part 2: Sec 18: 2014
348.	Endoscopic equipment	Cl. 201.14 programmable electrical medical systems (PEMS)	IEC 60601-2-18: 2009 IS 13450: Part 2: Sec 18: 2014
349.	Endoscopic equipment	Cl. 201.15 construction of ME equipment	IEC 60601-2-18: 2009 IS 13450: Part 2: Sec 18: 2014
350.	Endoscopic equipment	Cl. 201.16 ME systems	IEC 60601-2-18: 2009 IS 13450: Part 2: Sec 18: 2014
351.	Automated non-invasive sphygmomanometers	Cl. 201.4 general requirements	IS/IEC 80601-2-30: 2018
352.	Automated non-invasive sphygmomanometers	Cl. 201.5 general requirements for testing ME equipment	IS/IEC 80601-2-30: 2018
353.	Automated non-invasive sphygmomanometers	Cl. 201.6 classification of me equipment and ME systems	IS/IEC 80601-2-30: 2018
354.	Automated non-invasive sphygmomanometers	Cl. 201.7 ME equipment identification, marking and documents	IS/IEC 80601-2-30: 2018

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
355.	Automated non-invasive sphygmomanometers	Cl. 201.8 protection against electrical hazards from ME equipment	IS/IEC 80601-2-30: 2018
356.	Automated non-invasive sphygmomanometers	Cl. 201.9 protection against mechanical hazards of ME equipment and ME systems	IS/IEC 80601-2-30: 2018
357.	Automated non-invasive sphygmomanometers	Cl. 201.10 protection against unwanted and excessive radiation hazards (excluding cl 10.1 & 10.4 of IEC 60601-1/ IS 13450-1)	IS/IEC 80601-2-30: 2018
358.	Automated non-invasive sphygmomanometers	Cl. 201.11 protection against excessive temperatures and other hazards	IS/IEC 80601-2-30: 2018
359.	Automated non-invasive sphygmomanometers	Cl. 201.12 accuracy of controls and instruments and protection against hazardous outputs	IS/IEC 80601-2-30: 2018
360.	Automated non-invasive sphygmomanometers	Cl. 201.13 hazardous situations and fault conditions for ME equipment	IS/IEC 80601-2-30: 2018

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
361.	Automated non-invasive sphygmomanometers	Cl. 201.14 programmable electrical medical systems (PEMS)	IS/IEC 80601-2-30: 2018
362.	Automated non-invasive sphygmomanometers	Cl. 201.15 construction of ME equipment	IS/IEC 80601-2-30: 2018
363.	Automated non-invasive sphygmomanometers	Cl. 201.16 ME systems	IS/IEC 80601-2-30: 2018
364.	Automated non-invasive sphygmomanometers	Cl. 201.101 pressurization	IS/IEC 80601-2-30: 2018
365.	Automated non-invasive sphygmomanometers	Cl. 201.102 connection tubing and cuff connectors	IS/IEC 80601-2-30: 2018
366.	Automated non-invasive sphygmomanometers	Cl. 201.103 unauthorized access	IS/IEC 80601-2-30: 2018
367.	Automated non-invasive sphygmomanometers	Cl. 201.104 maximum inflating time	IS/IEC 80601-2-30: 2018
368.	Automated non-invasive sphygmomanometers	Cl. 201.105 automatic cycling modes	IS/IEC 80601-2-30: 2018
369.	Automated non-invasive sphygmomanometers	Cl. 201.106 clinical accuracy	IS/IEC 80601-2-30: 2018
370.	Automated non-invasive sphygmomanometers	Cl. 206 usability	IS/IEC 80601-2-30: 2018

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Sl. No.	**Product(s)/Material of Test**	**Specific Tests Performed**	**Test Method**
	Medical Electrical Equipment		
371.	Automated non-invasive sphygmomanometers	Cl. 210 requirements for the development of physiologic closed-loop controllers	IS/IEC 80601-2-30: 2018
372.	Automated non-invasive sphygmomanometers	Cl. 211 requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	IS/IEC 80601-2-30: 2018
373.	Automated non-invasive sphygmomanometers	Cl. 212 requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment	IS/IEC 80601-2-30: 2018