National Accreditation Board for Testing and Calibration Laboratories

CERTIFICATE OF ACCREDITATION

PSG CENTRE FOR INDUSTRIAL RESEARCH AND DEVELOPMENT

has been assessed and accredited in accordance with the standard

ISO/IEC 17025:2017

"General Requirements for the Competence of Testing & Calibration Laboratories"

for its facilities at

A 115, PSG COLLEGE OF TECHNOLOGY, AVINASHI ROAD, PEELAMEDU, COIMBATORE, TAMIL NADU, INDIA

in the field of

CALIBRATION

Certificate Number: CC-4660

Issue Date: 30/01/2026 **Valid Until:** 29/01/2030

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL.
(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Name of Legal Entity: P. S. GOVINDASWAMY NAIDU SONS & CHARITIES

Signed for and on behalf of NABL

Pankaj Johri
Director

Dr. Ramanand N. Shukla
Chief Executive Officer

SCOPE OF ACCREDITATION

Laboratory Name :	PSG CENTRE FOR INDUSTRIAL RESEARCH AND DEVELOPMENT, A 115, PSG COLLEGE OF TECHNOLOGY, AVINASHI ROAD, PEELAMEDU, COIMBATORE, TAMIL NADU, INDIA
Accreditation Standard	ISO/IEC 17025:2017
Certificate Number	CC-4660
Validity	30/01/2026 to 29/01/2030

Last Amended on -

S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrument	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
Permanent Facility					
1	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	BP Apparatus - Pulse Rate	Using Vital Sign Simulator by Direct Method	30 bpm to 150 bpm	4.22 bpm
2	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	BP Apparatus / Sphygmomanometer - Pressure (Leak Test)	Using Vital Sign Simulator by Direct Method	0 to 40 mmHg	5.8 mmHg
3	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	BP Apparatus / Sphygmomanometer - Pressure (NIBP)	Using Vital Sign Simulator by Direct Method	50 mmHg to 200 mmHg	5.8 mmHg
4	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow Meter with Humidifier - Pressure	Using Gas Flow Analyzer by Comparison Method	0 to 60 psi	1.95 %
5	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow Meter with Humidifier - Temperature	Using Digital Thermometer by Comparison Method	20 °C to 50 °C	1 °C

SCOPE OF ACCREDITATION

Laboratory Name : PSG CENTRE FOR INDUSTRIAL RESEARCH AND DEVELOPMENT, A 115, PSG COLLEGE OF TECHNOLOGY, AVINASHI ROAD, PEELAMEDU, COIMBATORE, TAMIL NADU, INDIA

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6	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow Meter with Humidifier / Flow Meter / Oxygen Concentrator - Flow	Using Gas Flow Analyzer by Comparison Method	1 lpm to 15 lpm	5.2 %
7	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Infusion Pump / Feeding Pump - Flow	Using Infusion Device Analyzer by Direct Method	5 ml/hr to 1000 ml/hr	4.28 %
8	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Infusion Pump / Feeding Pump - Occlusion Pressure	Using Infusion Device Analyzer by Direct Method	0 to 1300 mmHg	2.07 %
9	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Infusion Pump / Feeding Pump - Volume	Using Infusion Device Analyzer by Direct Method	1 ml to 400 ml	6.4 %
10	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Nebulizer - Flow	Using Gas Flow Analyzer by Comparison Method	7 lpm to 10 lpm	5 %
11	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Nebulizer - Pressure	Using Gas Flow Analyzer by Comparison Method	0 to 50 psi	4.97 %

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12	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pulse Oximeter - Heart Rate	Using SPO2 Functional Tester by Direct Method	30 bpm to 150 bpm	13.07 %
13	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pulse Oximeter - SPO2	Using SPO2 Functional Tester by Direct Method	80 % to 100 %	4.46 %
14	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Suction Pump - Flow	Using Gas Flow Analyzer by Comparison Method	1 lpm to 15 lpm	2.41 %
15	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Suction Pump - Vacuum	Using Gas Flow Analyzer by Comparison Method	0 to 600 mmHg	13.8 mmHg
16	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump - Flow	Using Infusion Device Analyzer by Direct method	5 ml/hr to 1000 ml/hr	4.28 %
17	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump - Occlusion Pressure	Using Infusion Device Analyzer by Direct Method	0 to 900 mmHg	4.29 %

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18	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump - Volume	Using Infusion Device Analyzer by Direct Method	1 ml to 50 ml	6.4 %
19	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump, Infusion Pump, Nebulizer, Pulse Oximeter, BP Apparatus, Suction Pump - Chassis/Enclosure Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 9000 µA	3.6 µA to 223 µA
20	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump, Infusion Pump, Nebulizer, Pulse Oximeter, BP Apparatus, Suction Pump - Earth Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 9000 µA	3.6 µA to 223 µA
21	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump, Infusion Pump, Nebulizer, Pulse Oximeter, BP Apparatus, Suction Pump - Insulation Resistance Test @ 500 V	Using Electrical Safety Analyzer by Direct Method	1 Mohm to 100 Mohm	8.98 %

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22	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump, Infusion Pump, Nebulizer, Pulse Oximeter, BP Apparatus, Suction Pump - Patient Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 1000 µA	3.6 µA to 24.5 µA
23	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump, Infusion Pump, Nebulizer, Pulse Oximeter, BP Apparatus, Suction Pump - Protective Earth Resistance	Using Electrical Safety Analyzer by Direct Method	0.1 ohm to 1.9 ohm	0.022 ohm to 0.058 ohm
24	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Machine - Chassis / Enclosure Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 9000 µA	3.6 µA to 223 µA
25	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Machine - Earth Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 10 mA	3.6 µA to 223 µA
26	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Machine - Insulation Resistance Test @ 500 V	Using Electrical Safety Analyzer by Direct Method	1 Mohm to 100 Mohm	3 %
27	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Machine - Patient Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 1000 µA	3.6 µA to 24.5 µA

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28	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Machine - Protective Earth Resistance	Using Electrical Safety Analyzer by Direct Method	0.05 ohm to 1.9 ohm	0.022 ohm to 0.058 ohm
29	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Machine / Recorder - ECG Output Amplitude	Using Defibrillator Analyzer by Direct Method	0.5 mV to 5 mV	4.8 %
30	MEDICAL DEVICES-IMAGING/PLOTTERS	Heart Rate - ECG Machine/Recorder, Monitors	Using Defibrillator Analyzer by Direct Method	30 bpm to 300 bpm	2.27 %
31	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - Chassis / Enclosure Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 9000 µA	3.6 µA to 223 µA
32	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - Earth Leakage Current	Using Electrical Safety Analyser by Direct Method	10 µA to 9000 µA	3.6 µA to 223 µA
33	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - ECG	Using Vital Sign Simulator by Direct Method	0.05 mV to 5 mV	6.26 %
34	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - Heart Rate	Using SPO2 Simulator and Vital Sign Simulator by Direct Method	30 BPM to 300 BPM	2.27 %

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35	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - Invasive Blood Pressure Accuracy	Using SPO2 Simulator and Vital Sign Simulator by Direct Method	0 to 200 mmHg	5.33 %
36	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - Non Invasive Blood Pressure	Using Vital Sign Simulator by Direct Method	50 to 400 mmHg	5.8 mmHg
37	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - Non Invasive Blood Pressure (Leak Test)	Using Vital Sign Simulator by Direct Method	50 mmHg to 400 mmHg	1.3 mmHg
38	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - Patient Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 1000 µA	3.6 µA to 24.5 µA
39	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - Protective Earth Resistance	Using Electrical Safety Analyzer by Direct Method	0.05 ohm to 1.9 ohm	0.022 ohm to 0.058 ohm
40	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - Respiration Rate	Using Vital Sign Simulator by Direct Method	10 brpm to 100 brpm	6.6 %
41	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - SPO2	Using SPO2 Simulator by Direct Method	70 % to 100 %	4.48 %

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42	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor, Syringe / Infusion Pump, Defibrillator, Suction Pump, ECG Unit, Electro - Surgical Unit, Autoclave, Radiant Warmer, Patient Warmer, Infant Incubator - Insulation Resistance @ 500 V	Using Electrical Safety Analyzer by Direct Method	1 Mohm to 100 Mohm	8.98 %
43	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Autoclave - Pressure	Using Digital Pressure Gauge by Comparison Method	0 to 2 bar	0.1 bar
44	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Autoclave - Temperature	Using Digital Thermometer with Logger by Comparison Method	50 °C to 125 °C	1.3 °C
45	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Autoclave - Time	Using Digital Timer by Comparison Method	1 s to 45 Min	0.1 s to 10 s

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46	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - Charge Time	Using Defibrillator Analyzer by Direct Method	1.5 s to 10 s	0.17 s
47	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - ECG Amplitude	Using Defibrillator Analyzer by Direct Method	0.5 mV to 5 mV	6.26 %
48	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - Energy	Using Defibrillator Analyzer by Direct Method	20 J to 300 J	7.5 J
49	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - Heart Rate	Using Defibrillator Analyzer by Direct Method	30 bpm to 300 bpm	1.6 % to 2.27 %
50	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - NIBP	Using Vital Signs Simulator by Direct Method	50 mmHg to 200 mmHg	5.8 mmHg

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51	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - SPO2	Using SPO2 Functional Tester by Direct Method	80 % to 100 %	4.46 %
52	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator, Infant Incubator, Electro Surgical Unit / Diathermy Machine / Cautery Machine, Autoclave, Patient Warmer, Radiant Warmer - Chassis / Enclosure Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 9000 µA	3.6 µA to 223 µA
53	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator, Infant Incubator, Electro Surgical Unit / Diathermy Machine / Cautery Machine, Autoclave, Patient Warmer, Radiant Warmer - Earth Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 9000 µA	3.6 µA to 223 µA

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54	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator, Infant Incubator, Electro Surgical Unit / Diathermy Machine / Cautery Machine, Autoclave, Patient Warmer, Radiant Warmer - Insulation Resistance Test @ 500 V	Using Electrical Safety Analyzer by Direct Method	1 Mohm to 100 Mohm	8.98 %
55	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator, Infant Incubator, Electro Surgical Unit / Diathermy Machine / Cautery Machine, Autoclave, Patient Warmer, Radiant Warmer - Patient Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 1000 µA	3.6 µA to 24.5 µA
56	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator, Infant Incubator, Electro Surgical Unit / Diathermy Machine / Cautery Machine, Autoclave, Patient Warmer, Radiant Warmer - Protective Earth Resistance	Using Electrical Safety Analyser by Direct Method	0.1 ohm to 1.9 ohm	0.022 ohm to 0.058 ohm

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57	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Electro Surgical Unit / Diathermy Machine / Cautery Machine - HF Leakage	Using Electro Surgery Analyzer by Direct Method	11 mA to 150 mA	1.62 mA to 5.64 mA
58	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Electro Surgical Unit / Diathermy Machine / Cautery Machine - Power	Using Electro Surgery Analyzer by Direct Method	10 W to 300 W	8.48 %
59	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Electro Surgical Unit / Diathermy Machine / Cautery Machine - REM	Using Electro Surgery Analyzer by Direct Method	10 ohm to 475 ohm	3.08 %
60	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Pacemaker / Defibrillator - Pacer Output	Using Defibrillator analyzer by Direct Method	2 mA to 20 mA	3.8 %
61	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Pacemaker / Defibrillator - Pacer Rate	Using Defibrillator analyzer by Direct Method	30 ppm to 180 ppm	1.92 %

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62	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Patient Warmer - Temperature	Using Digital Thermometer with Logger by Comparison Method	30 °C to 45 °C	1 °C
63	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Radiant Warmer - Temperature	Using Digital Thermometer with Logger by Comparison Method	30 °C to 40 °C	1.2 °C

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Site Facility					
1	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	BP Apparatus - Pulse Rate	Using Vital Sign Simulator by Direct Method	30 bpm to 150 bpm	4.22 bpm
2	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	BP Apparatus / Sphygmomanometer - Pressure (Leak Test)	Using Vital Sign Simulator by Direct Method	0 to 40 mmHg	5.8 mmHg
3	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	BP Apparatus / Sphygmomanometer - Pressure (NIBP)	Using Vital Sign Simulator by Direct Method	50 mmHg to 200 mmHg	5.8 mmHg
4	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow Meter with Humidifier - Pressure	Using Gas Flow Analyzer by Comparison Method	0 to 60 psi	1.95 %
5	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow Meter with Humidifier - Temperature	Using Digital Thermometer by Comparison Method	20 °C to 50 °C	1 °C

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6	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow Meter with Humidifier / Flow Meter / Oxygen Concentrator - Flow	Using Gas Flow Analyzer by Comparison Method	1 lpm to 15 lpm	5.2 %
7	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Infusion Pump / Feeding Pump - Flow	Using Infusion Device Analyzer by Direct Method	5 ml/hr to 1000 ml/hr	4.28 %
8	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Infusion Pump / Feeding Pump - Occlusion Pressure	Using Infusion Device Analyzer by Direct Method	0 to 1300 mmHg	2.07 %
9	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Infusion Pump / Feeding Pump - Volume	Using Infusion Device Analyzer by Direct Method	1 ml to 400 ml	6.4 %
10	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Nebulizer - Flow	Using Gas Flow Analyzer by Comparison Method	7 lpm to 10 lpm	5 %
11	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Nebulizer - Pressure	Using Gas Flow Analyzer by Comparison Method	0 to 50 psi	4.97 %

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12	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pulse Oximeter - Heart Rate	Using SPO2 Functional Tester by Direct Method	30 bpm to 150 bpm	13.07 %
13	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pulse Oximeter - SPO2	Using SPO2 Functional Tester by Direct Method	80 % to 100 %	4.46 %
14	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Suction Pump - Flow	Using Gas Flow Analyzer by Comparison Method	1 lpm to 15 lpm	2.41 %
15	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Suction Pump - Vacuum	Using Gas Flow Analyzer by Comparison Method	0 to 600 mmHg	13.8 mmHg
16	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump - Flow	Using Infusion Device Analyzer by Direct method	5 ml/hr to 1000 ml/hr	4.28 %
17	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump - Occlusion Pressure	Using Infusion Device Analyzer by Direct Method	0 to 900 mmHg	4.29 %

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S.No	Discipline / Group	Measurand or Reference Material/Type of instrument or material to be calibrated or measured / Quantity Measured /Instrument	Calibration or Measurement Method or procedure	Measurement range and additional parameters where applicable(Range and Frequency)	* Calibration and Measurement Capability(CMC)(±)
18	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump - Volume	Using Infusion Device Analyzer by Direct Method	1 ml to 50 ml	6.4 %
19	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump, Infusion Pump, Nebulizer, Pulse Oximeter, BP Apparatus, Suction Pump - Chassis/Enclosure Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 9000 µA	3.6 µA to 223 µA
20	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump, Infusion Pump, Nebulizer, Pulse Oximeter, BP Apparatus, Suction Pump - Earth Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 9000 µA	3.6 µA to 223 µA
21	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump, Infusion Pump, Nebulizer, Pulse Oximeter, BP Apparatus, Suction Pump - Insulation Resistance Test @ 500 V	Using Electrical Safety Analyzer by Direct Method	1 Mohm to 100 Mohm	8.98 %

SCOPE OF ACCREDITATION

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22	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump, Infusion Pump, Nebulizer, Pulse Oximeter, BP Apparatus, Suction Pump - Patient Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 1000 µA	3.6 µA to 24.5 µA
23	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump, Infusion Pump, Nebulizer, Pulse Oximeter, BP Apparatus, Suction Pump - Protective Earth Resistance	Using Electrical Safety Analyzer by Direct Method	0.1 ohm to 1.9 ohm	0.022 ohm to 0.058 ohm
24	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Machine - Chassis / Enclosure Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 9000 µA	3.6 µA to 223 µA
25	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Machine - Earth Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 10 mA	3.6 µA to 223 µA
26	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Machine - Insulation Resistance Test @ 500 V	Using Electrical Safety Analyzer by Direct Method	1 Mohm to 100 Mohm	3 %
27	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Machine - Patient Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 1000 µA	3.6 µA to 24.5 µA

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28	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Machine - Protective Earth Resistance	Using Electrical Safety Analyzer by Direct Method	0.05 ohm to 1.9 ohm	0.022 ohm to 0.058 ohm
29	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Machine / Recorder - ECG Output Amplitude	Using Defibrillator Analyzer by Direct Method	0.5 mV to 5 mV	4.8 %
30	MEDICAL DEVICES-IMAGING/PLOTTERS	Heart Rate - ECG Machine/Recorder, Monitors	Using Defibrillator Analyzer by Direct Method	30 bpm to 300 bpm	2.27 %
31	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - Chassis / Enclosure Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 9000 µA	3.6 µA to 223 µA
32	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - Earth Leakage Current	Using Electrical Safety Analyser by Direct Method	10 µA to 9000 µA	3.6 µA to 223 µA
33	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - ECG	Using Vital Sign Simulator by Direct Method	0.05 mV to 5 mV	6.26 %
34	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - Heart Rate	Using SPO2 Simulator and Vital Sign Simulator by Direct Method	30 BPM to 300 BPM	2.27 %

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35	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - Invasive Blood Pressure Accuracy	Using SPO2 Simulator and Vital Sign Simulator by Direct Method	0 to 200 mmHg	5.33 %
36	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - Non Invasive Blood Pressure	Using Vital Sign Simulator by Direct Method	50 to 400 mmHg	5.8 mmHg
37	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - Non Invasive Blood Pressure (Leak Test)	Using Vital Sign Simulator by Direct Method	50 mmHg to 400 mmHg	1.3 mmHg
38	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - Patient Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 1000 µA	3.6 µA to 24.5 µA
39	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - Protective Earth Resistance	Using Electrical Safety Analyzer by Direct Method	0.05 ohm to 1.9 ohm	0.022 ohm to 0.058 ohm
40	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - Respiration Rate	Using Vital Sign Simulator by Direct Method	10 brpm to 100 brpm	6.6 %
41	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor / Multipara Monitor - SPO2	Using SPO2 Simulator by Direct Method	70 % to 100 %	4.48 %

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42	MEDICAL DEVICES-MONITORING UNIT	Patient Monitor, Syringe / Infusion Pump, Defibrillator, Suction Pump, ECG Unit, Electro - Surgical Unit, Autoclave, Radiant Warmer, Patient Warmer, Infant Incubator - Insulation Resistance @ 500 V	Using Electrical Safety Analyzer by Direct Method	1 Mohm to 100 Mohm	8.98 %
43	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Autoclave - Pressure	Using Digital Pressure Gauge by Comparison Method	0 to 2 bar	0.1 bar
44	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Autoclave - Temperature	Using Digital Thermometer with Logger by Comparison Method	50 °C to 125 °C	1.3 °C
45	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Autoclave - Time	Using Digital Timer by Comparison Method	1 s to 45 Min	0.1 s to 10 s

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46	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - Charge Time	Using Defibrillator Analyzer by Direct Method	1.5 s to 10 s	0.17 s
47	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - ECG Amplitude	Using Defibrillator Analyzer by Direct Method	0.5 mV to 5 mV	6.26 %
48	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - Energy	Using Defibrillator Analyzer by Direct Method	20 J to 300 J	7.5 J
49	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - Heart Rate	Using Defibrillator Analyzer by Direct Method	30 bpm to 300 bpm	1.6 % to 2.27 %
50	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - NIBP	Using Vital Signs Simulator by Direct Method	50 mmHg to 200 mmHg	5.8 mmHg

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51	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - SPO2	Using SPO2 Functional Tester by Direct Method	80 % to 100 %	4.46 %
52	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator, Infant Incubator, Electro Surgical Unit / Diathermy Machine / Cautery Machine, Autoclave, Patient Warmer, Radiant Warmer - Chassis / Enclosure Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 9000 µA	3.6 µA to 223 µA
53	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator, Infant Incubator, Electro Surgical Unit / Diathermy Machine / Cautery Machine, Autoclave, Patient Warmer, Radiant Warmer - Earth Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 9000 µA	3.6 µA to 223 µA

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54	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator, Infant Incubator, Electro Surgical Unit / Diathermy Machine / Cautery Machine, Autoclave, Patient Warmer, Radiant Warmer - Insulation Resistance Test @ 500 V	Using Electrical Safety Analyzer by Direct Method	1 Mohm to 100 Mohm	8.98 %
55	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator, Infant Incubator, Electro Surgical Unit / Diathermy Machine / Cautery Machine, Autoclave, Patient Warmer, Radiant Warmer - Patient Leakage Current	Using Electrical Safety Analyzer by Direct Method	10 µA to 1000 µA	3.6 µA to 24.5 µA
56	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator, Infant Incubator, Electro Surgical Unit / Diathermy Machine / Cautery Machine, Autoclave, Patient Warmer, Radiant Warmer - Protective Earth Resistance	Using Electrical Safety Analyser by Direct Method	0.1 ohm to 1.9 ohm	0.022 ohm to 0.058 ohm

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57	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Electro Surgical Unit / Diathermy Machine / Cautery Machine - HF Leakage	Using Electro Surgery Analyzer by Direct Method	11 mA to 150 mA	1.62 mA to 5.64 mA
58	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Electro Surgical Unit / Diathermy Machine / Cautery Machine - Power	Using Electro Surgery Analyzer by Direct Method	10 W to 300 W	8.48 %
59	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Electro Surgical Unit / Diathermy Machine / Cautery Machine - REM	Using Electro Surgery Analyzer by Direct Method	10 ohm to 475 ohm	3.08 %
60	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Pacemaker / Defibrillator - Pacer Output	Using Defibrillator analyzer by Direct Method	2 mA to 20 mA	3.8 %
61	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Pacemaker / Defibrillator - Pacer Rate	Using Defibrillator analyzer by Direct Method	30 ppm to 180 ppm	1.92 %

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62	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Patient Warmer - Temperature	Using Digital Thermometer with Logger by Comparison Method	30 °C to 45 °C	1 °C
63	MEDICAL DEVICES- PATIENT CONDITIONING / MAINTENANCE	Radiant Warmer - Temperature	Using Digital Thermometer with Logger by Comparison Method	30 °C to 40 °C	1.2 °C

*** CMCs represent expanded uncertainties expressed at approximately the 95% level of confidence, using a coverage factor of *k* = 2.**