National Accreditation Board for Testing and Calibration Laboratories

CERTIFICATE OF ACCREDITATION

ROOTS METROLOGY & TESTING LABORATORY

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

156, BOMMASANDRA INDUSTRIAL AREA, BOMMASANDRA - JIGANI LINK ROAD, ANEKAL TALUK, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

in the field of

CALIBRATION

Certificate Number: CC-2782

Issue Date: 21/10/2023 **Valid Until:** 20/10/2025

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 thislaboratory, you may also visit NABL website www.nabl-india.org)

Name of Legal Entity: Roots Industries India Private Limited

Signed for and on behalf of NABL

N. Venkateswaran
Chief Executive Officer

SCOPE OF ACCREDITATION

Laboratory Name :	ROOTS METROLOGY & TESTING LABORATORY, 156, BOMMASANDRA INDUSTRIAL AREA, BOMMASANDRA - JIGANI LINK ROAD, ANEKAL TALUK, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA
Accreditation Standard	ISO/IEC 17025:2017
Certificate Number	CC-2782
Validity	21/10/2023 to 20/10/2025

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 (Sphygmomanometer) - Pressure	Using Vital sign simulator by Comparison method	30 mmHg to 300 mmHg	7.8%
2	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Electrical Safety Common - Voltage (Suction Pump,Nebulizer,Infusion Pump,Syringe Pump,Enternal Feeding Pump,Anesthesia M/C,Pulse Oxymeter)	Using Electrical Safety Analyzer by Direct Method	90 V to 240 V	8.13%
3	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Enclosure leakage current NC - Suction Pump,Nebulizer,Infusion Pump,Syringe Pump,Enternal Feeding Pump,Anesthesia M/C,Pulse Oxymeter	Using Electrical Safety Analyzer by Direct Method	4 µA to 100 µA	0.90 µA

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4	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Enclosure leakage current SFC - Suction Pump,Nebulizer,Infusion Pump,Syring Pump,Enternal Feeding Pump,Anesthesia M/C,Pulse Oxymeter	Using Electrical Safety Analyzer by Direct Method	4 µA to 500 µA	0.92 µA
5	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow Rate - Enteral Feeding Pump	Using Infusion Pump Analyzer by Comparison method	10 ml/hr to 300 ml/hr	5.91%
6	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Ground Wire Resistance - Suction Pump,Nebulizer,Infusion Pump,Syringe Pump,Enternal Feeding Pump,Anesthesia M/C,Pulse Oxymeter)	Using Electrical Safety Analyzer by Direct Method	0.1 ohm to 2 ohm	9.57%
7	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Infusion Pump - Flow Rate	Using Infusion Pump Analyzer by Comparison method	10 ml/h to 300 ml/h	8.43%

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8	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Infusion Pump - Occlusion Pressure	Using Infusion Pump Analyzer by Comparison method	0 to 1500 mmHg	3.16%
9	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Infusion Pump - Volume	Using Infusion Pump Analyzer by Comparison method	5 ml to 400 ml	1.95%
10	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Nebulizer - Flow	Using Gas Flow Analyzer by Comparison Method	2 lpm to 30 lpm	4.83%
11	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Patient Lead Leakage Current and Earth Leakage Current - Suction Pump,Nebulizer,Infusion Pump,Syring Pump,Enternal Feeding Pump,Anesthesia M/C,Pulse Oxymeter	Using Electrical Safety Analyzer by Direct Method	4 µA to 8 mA	0.91 µA
12	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pressure - Pressure Gauge of Oxygen Cylinder	Using Digital Pressure gauge by comparison method	0 to 10 bar	0.091bar

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13	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pulse Rate - Pulse Oxymeters	Using Vital Sign Simulator with SpO2 Test Module by Simulation Method	30 bpm to 240 bpm	5.65%
14	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	SPO2 - Pulse Oxymeters	Using Vital Sign Simulator with SpO2 Test Module by Simulation Method	70 % to 100 %	5.32%
15	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Suction Apparatus - Vacuum	Using Digital Vacuum gauge by Comparison Method	(-)14 Psi to 0	0.12psi
16	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump - Flow Rate	Using Infusion Pump Analyzer by Comparison method	10 ml/h to 300 ml/h	8.40%
17	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump - Occlusion Pressure	Using Infusion Pump Analyzer by Comparison method	0 to 1500 mmHg	3.16%
18	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump - Volume	Using Infusion Pump Analyzer by Comparison Method	5 ml to 50 ml	8.40%

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19	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Volume - Enteral Feeding Pump	Using Infusion Pump Analyzer by Comparison method	5 ml to 400 ml	6.10%
20	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Machine - Amplitude	Using Vital sign simulator by Simulation Method	0.5 mV to 5.0 mV	4.77%
21	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Machine - Heart Rate	Using Vital sign simulator by Simulation Method	30 bpm to 300 bpm	4.74%
22	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Common - Enclosure leakage current NC (Trans illuminator light source, EEG, ECG)	Using Electrical Safety Analyzer by Direct Method	4 µA to 100 µA	0.90 µA
23	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Common - Enclosure leakage current SFC (Trans illuminator light source, EEG, ECG)	Using Electrical Safety Analyzer by Direct Method	4 µA to 500 µA	0.92 µA

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24	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Common - Ground Wire Resistance (Trans illuminator light source, EEG, ECG)	Using Electrical Safety Analyzer by Direct Method	0.1 ohm to 2 ohm	9.57%
25	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Common - Patient Lead Leakage Current and Earth Leakage Current (Trans illuminator light source, EEG, ECG)	Using Electrical Safety Analyzer by Direct Method	4 µA to 8 mA	0.91 µA
26	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Common - Voltage (Trans illuminator light source, EEG, ECG)	Using Electrical Safety Analyzer by Direct Method	90 V to 240 V	8.13%
27	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Common- Insulation Test (Trans illuminator light source, EEG, ECG)	Using Electrical Safety Analyzer by Direct Method	0.10 Mohm to 100 Mohm	8.1%
28	MEDICAL DEVICES-IMAGING/PLOTTERS	Fetal Heart Rate (FHR) - Fetal Doppler	Using Fetal Simulator by Direct Method	60 bpm to 240 bpm	4.61%

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29	MEDICAL DEVICES-IMAGING/PLOTTERS	OT Light, Examination Light, Slit Lamp	Using Digital Illuminance / Lux Meter by Comparison Method	20000 Lux to 100000 Lux	7.44%
30	MEDICAL DEVICES-IMAGING/PLOTTERS	OT Light, Examination Light,Light Source,Slit Lamp	Using Digital Illuminance / Lux Meter by Comparison Method	100 Lux to 20000 Lux	7.44%
31	MEDICAL DEVICES-IMAGING/PLOTTERS	Trans illuminator Light Source,Endoscopy Unit	Using Digital Illuminance / Lux Meter by Comparison Method	10000 Lux to 100000 Lux	7.44%
32	MEDICAL DEVICES-MONITORING UNIT	Electrical Safety - Voltage - Patient Monitors, Apnea Monitors, Fetal monitors, Therapeutic Stimulator, Hematology Analyzer	Using Electrical Safety Analyzer by Direct Method	90 V to 240 V	7.59%
33	MEDICAL DEVICES-MONITORING UNIT	Enclosure leakage current NC - Patient Monitors, Apnea Monitors, Fetal monitors, Therapeutic Stimulator, Hematology Analyzer	Using Electrical Safety Analyzer by Direct Method	4 µA to 100 µA	0.90 µA

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34	MEDICAL DEVICES-MONITORING UNIT	Enclosure leakage current SFC - Patient Monitors, Apnea Monitors, Fetal monitors, Therapeutic Stimulator, Hematology Analyzer	Using Electrical Safety Analyzer by Direct Method	4 µA to 500 µA	0.92 µA
35	MEDICAL DEVICES-MONITORING UNIT	Fetal Electrocardiograph (fECG) - Fetal Monitor	Using Fetal Simulator by Simulation Method	0.5 mV to 2 mV	3.33%
36	MEDICAL DEVICES-MONITORING UNIT	Fetal Heart Rate (FHR) - Fetal Monitor	Using Fetal Simulator by Simulation Method	60 bpm to 240 bpm	4.61%
37	MEDICAL DEVICES-MONITORING UNIT	Ground Wire Resistance - Patient Monitors, Apnea Monitors, Fetal monitors, Therapeutic Stimulator, Hematology Analyzer	Using Electrical Safety Analyzer by Direct Method	0.1 ohm to 2 ohm	9.57%
38	MEDICAL DEVICES-MONITORING UNIT	Heart Rate - Apnea Monitor	Using Vital Sign Simulator by Simulation Method	30 bpm to 300 bpm	4.66%

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39	MEDICAL DEVICES-MONITORING UNIT	Insulation Test - Patient Monitors, Apnea Monitors, Fetal monitors, Therapeutic Stimulator, Hematology Analyzer	Using Electrical Safety Analyzer by Direct Method	0.10 Mohm to 100 Mohm	8.10%
40	MEDICAL DEVICES-MONITORING UNIT	Maternal Electrocardiograph (mECG) - Fetal Monitor	Using Fetal Simulator by Simulation Method	0.5 mV to 2 mV	4.85%
41	MEDICAL DEVICES-MONITORING UNIT	Maternal Heart Rate (MHR) - Fetal Monitor	Using Fetal Simulator by Simulation Method	60 bpm to 160 bpm	2.62%
42	MEDICAL DEVICES-MONITORING UNIT	Patient Lead Leakage Current and Earth Leakage Current - Patient Monitors, Apnea Monitors, Fetal monitors, Therapeutic Stimulator, Hematology Analyzer	Using Electrical Safety Analyzer by Direct Method	4 µA to 8 mA	0.91 µA
43	MEDICAL DEVICES-MONITORING UNIT	Patient Monitors - Heart Rate, Pulse Rate (NIBP Apparatus)	Using Vital sign simulator by Simulation Method	30 bpm to 300 bpm	4.82%

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44	MEDICAL DEVICES-MONITORING UNIT	Patient Monitors, NIBP Apparatus - NIBP (Dynamic) Manometer (Systolic and Diastolic)	Using Vital sign simulator by Simulation Method	0 to 300 mmHg	6.02%
45	MEDICAL DEVICES-MONITORING UNIT	Pulse Rate - Patient Monitors	Using Vital Sign Simulator with SpO2 Test Module by Simulation Method	30 bpm to 240 bpm	4.95%
46	MEDICAL DEVICES-MONITORING UNIT	SPO2 - Patient Monitors	Using Vital Sign Simulator with SpO2 Test Module by Simulation Method	70 % to 100 %	6.70%
47	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - Charge Time	Using Defibrillator / Pacemaker Analyzer by Comparison Method	0 to 15 s	4.01%
48	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - NIBP	Using Vital Sign Simulator by Simulation Method	50 mmHg to 300 mmHg	2.41%

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49	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - Output Energy	Using Defibrillator / Pacemaker Analyzer by Comparison Method	20 Joules to 300 Joules	3.18%
50	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - SpO2 Percentage	Using Vital Sign Simulator with SpO2 Test Module by Simulation Method	70 % to 100 %	6.7%
51	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - Synchronization	Using Defibrillator / Pacemaker Analyzer by Comparison Method	0 to 60 msec	5.5%
52	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Electrical Safety - Insulation Test (Incubator, Defibrillator, Ventilator, Electro Surgical Unit/ Diathermy Machine, Electronic Tourniquet, Dialysis Machine, Patient Warmer, OT Table, Radiant Warmer	Using Electrical Safety Analyzer by Direct Method	0.10 Mohm to 100 Mohm	8.1%

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53	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Electrical Safety Common - Voltage (Incubator, Defibrillator, Ventilator, Electro Surgical Unit/ Diathermy Machine, Electronic Tourniquet, Dialysis Machine, Patient Warmer, OT Table, Radiant Warmer)	Using Electrical Safety Analyzer by Direct Method	90 V to 240 V	7.81%
54	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Electro Surgical Unit / Diathermy machine / Cautry Machine - Output Power	Using Electrosurgical Analyzer by Comparison method	10 W to 300 W	8.56%
55	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Electronic Tourniquet - Pressure	Using Vital Sign Simulator, Stop Watch by Comparison method	0 to 400 mmHg	2.41%
56	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Electronic Tourniquet - Time Interval	Using Stop Watch by Comparison method	1 s to 15 min	1.86s

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57	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Enclosure leakage current NC (Incubator, Defibrillator, Ventilator, Electro Surgical Unit/ Diathermy Machine, Electronic Tourniquet, Dialysis Machine, Patient Warmer, OT Table, Radiant warmer)	Using Electrical Safety Analyzer by Direct Method	4 µA to 100 µA	0.90 µA
58	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Enclosure leakage current SFC - (Incubator, Defibrillator, Ventilator, Electro Surgical Unit/ Diathermy Machine, Electronic Tourniquet, Dialysis Machine, Patient Warmer, OT Table, Radiant warmer)	Using Electrical Safety Analyzer by Direct Method	4 µA to 500 µA	0.92 µA
59	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	External Pace Maker - Pacer Current	Using Defibrillator Analyzer by Comparison Method	8 mA to 100 mA	6.90%

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60	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	External Pacemaker - Pacer Rate	Using Defibrillator Analyzer by Comparison Method	20 ppm to 300 ppm	9.96%
61	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Ground Wire Resistance (Incubator, Defibrillator, Ventilator, Electro Surgical Unit/ Diathermy Machine, Electronic Tourniquet, Dialysis Machine, Patient Warmer, OT Table, Radiant warmer)	Using Electrical Safety Analyzer by Direct Method	0.1 ohm to 2 ohm	9.57%
62	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Patient Leakage Current, Earth Leakage Current (Incubator, Defibrillator, Ventilator, Electro Surgical Unit, Electronic Tourniquet, Dialysis Machine, Patient Warmer, OT Table, Radiant Warmer)	Using Electrical Safety Analyzer by Direct Method	4 µA to 8 mA	0.91 µA

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Site Facility					
1	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Anesthesia Workstation - Flow	Using Gas Flow Analyzer by Comparison method	1 lpm to 15 lpm	0.78lpm
2	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Anesthesia Workstation - Positive End Expiratory Pressure (PEEP)	Using Gas Flow Analyzer by Comparison method	10 cmH2O to 145 cmH2O	7.66%
3	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Bilevel Positive Airway Pressure Machine (BiPAP) - Expiratory Positive Airway Pressure (EPAP)	Using Gas Flow Analyzer by Comparison Method	0 to 145 cmH2O	5.99%
4	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Bilevel Positive Airway Pressure Machine (BiPAP) - Inspiratory Positive Airway Pressure (IPAP)	Using Gas Flow Analyzer by Comparison Method	0 to 145 cmH2O	5.99%
5	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Boyles Apparatus - Flow	Using Gas Flow Analyzer by Comparison method	1 lpm to 15 lpm	0.79lpm

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6	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Boyles Apparatus - Pressure	Using Digital Pressure gauge by comparison method	0 to 250 bar	5.78bar
7	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	BP apparatus (Sphygmomanometer) - Pressure	Using Vital sign simulator by Comparison method	30 mmHg to 300 mmHg	7.8%
8	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Continuous Positive Airway Pressure Machine (CPAP) - Flow	Using Gas flow Analyzer by Comparison Method	4 lpm to 15 lpm	10.89%
9	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Continuous Positive Airway Pressure Machine (CPAP) - Pressure	Using Gas Flow Analyzer by Comparison method	4 cmH2O to 20 cmH2O	10.04%
10	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Electrical Safety Common - Voltage (Suction Pump,Nebulizer,Infusion Pump,Syringe Pump,Enternal Feeding Pump,Anesthesia M/C,Pulse Oxymeter)	Using Electrical Safety Analyzer by Direct Method	90 V to 240 V	8.13%

SCOPE OF ACCREDITATION

Laboratory Name : ROOTS METROLOGY & TESTING LABORATORY, 156, BOMMASANDRA INDUSTRIAL AREA, BOMMASANDRA - JIGANI LINK ROAD, ANEKAL TALUK, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

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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)(±)
11	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Enclosure leakage current NC - Suction Pump,Nebulizer,Infusion Pump,Syringe Pump,Enternal Feeding Pump,Anesthesia M/C,Pulse Oxymeter	Using Electrical Safety Analyzer by Direct Method	4 µA to 100 µA	0.90 µA
12	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Enclosure leakage current SFC - Suction Pump,Nebulizer,Infusion Pump,Syring Pump,Enternal Feeding Pump,Anesthesia M/C,Pulse Oxymeter	Using Electrical Safety Analyzer by Direct Method	4 µA to 500 µA	0.92 µA
13	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow - CO2 Insufflator	Using Gas Flow Analyzer by Comparison method	1 lpm to 30 lpm	7.84%
14	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow - Oxygen Concentrator	Using Gas Flow Analyzer by Comparison method	1 lpm to 5 lpm	10.25%

SCOPE OF ACCREDITATION

Laboratory Name : ROOTS METROLOGY & TESTING LABORATORY, 156, BOMMASANDRA INDUSTRIAL AREA, BOMMASANDRA - JIGANI LINK ROAD, ANEKAL TALUK, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

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15	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow meter - Flow	Using Gas flow Analyzer by Comparison Method	1 lpm to 15 lpm	0.79lpm
16	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Flow Rate - Enteral Feeding Pump	Using Infusion Pump Analyzer by Comparison method	10 ml/hr to 300 ml/hr	5.91%
17	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Ground Wire Resistance - Suction Pump,Nebulizer,Infusion Pump,Syringe Pump,Enternal Feeding Pump,Anesthesia M/C,Pulse Oxymeter)	Using Electrical Safety Analyzer by Direct Method	0.1 ohm to 2 ohm	9.57%
18	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Infusion Pump - Flow Rate	Using Infusion Pump Analyzer by Comparison method	10 ml/h to 300 ml/h	8.43%
19	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Infusion Pump - Occlusion Pressure	Using Infusion Pump Analyzer by Comparison method	0 to 1500 mmHg	3.16%

SCOPE OF ACCREDITATION

Laboratory Name : ROOTS METROLOGY & TESTING LABORATORY, 156, BOMMASANDRA INDUSTRIAL AREA, BOMMASANDRA - JIGANI LINK ROAD, ANEKAL TALUK, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

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20	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Infusion Pump - Volume	Using Infusion Pump Analyzer by Comparison method	5 ml to 400 ml	1.95%
21	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Inspiratory Time (Ti), Expiratory Time (Te) for I:E Ratio - Anesthesia Machine	Using Gas Flow Analyzer by Comparison method	4:1 to 1:4	4.71%
22	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Inspiratory Time (Ti), Expiratory Time (Te) for I:E Ratio - BiPAP	Using Gas Flow Analyzer by Comparison Method	4:1 to 1:4	4.71%
23	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Insulation Test - Suction Pump,Nebulizer,Infusion Pump,Syringe Pump,Enternal Feeding Pump,Anesthesia M/C,Pulse Oxymeter	Using Electrical Safety Analyzer by Direct Method	0.10 Mohm to 100 Mohm	8.1%
24	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Nebulizer - Flow	Using Gas Flow Analyzer by Comparison Method	2 lpm to 30 lpm	4.83%

SCOPE OF ACCREDITATION

Laboratory Name : ROOTS METROLOGY & TESTING LABORATORY, 156, BOMMASANDRA INDUSTRIAL AREA, BOMMASANDRA - JIGANI LINK ROAD, ANEKAL TALUK, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

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25	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Oxygen Percentage - Anesthesia Machine,Oxygen Concentrator	Using Gas Flow Analyzer by Comparison method	21 % to 100 %	3.84%
26	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Patient Lead Leakage Current and Earth Leakage Current - Suction Pump,Nebulizer,Infusion Pump,Syring Pump,Enternal Feeding Pump,Anesthesia M/C,Pulse Oxymeter	Using Electrical Safety Analyzer by Direct Method	4 µA to 8 mA	0.91 µA
27	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Peak Inspiratory Pressure (PIP) - Anesthesia Machine	Using Gas Flow Analyzer by Comparison method	0 to 145 cmH2O	5.99%
28	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pressure - CO2 Insufflator	Using Gas Flow Analyzer by Comparison method	0 to 40 mmHg	2.16%
29	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pressure - Pressure Gauge of Oxygen Cylinder	Using Digital Pressure gauge by comparison method	0 to 10 bar	0.091bar

SCOPE OF ACCREDITATION

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30	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Pulse Rate - Pulse Oxymeters	Using Vital Sign Simulator with SpO2 Test Module by Simulation Method	30 bpm to 240 bpm	5.65%
31	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Respiration Rate (RR) - Anesthesia Machine	Using Gas Flow Analyzer by Comparison method	2 brpm to 150 brpm	6.42%
32	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Respiration Rate (RR) - BiPAP	Using Gas Flow Analyzer by Comparison Method	2 brpm to 150 brpm	5.46%
33	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	SPO2 - Pulse Oxymeters	Using Vital Sign Simulator with SpO2 Test Module by Simulation Method	70 % to 100 %	5.32%
34	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Suction Apparatus - Vacuum	Using Digital Vacuum gauge by Comparison Method	(-)14 Psi to 0	0.12psi
35	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump - Flow Rate	Using Infusion Pump Analyzer by Comparison method	10 ml/h to 300 ml/h	8.40%

SCOPE OF ACCREDITATION

Laboratory Name : ROOTS METROLOGY & TESTING LABORATORY, 156, BOMMASANDRA INDUSTRIAL AREA, BOMMASANDRA - JIGANI LINK ROAD, ANEKAL TALUK, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

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36	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump - Occlusion Pressure	Using Infusion Pump Analyzer by Comparison method	0 to 1500 mmHg	3.16%
37	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Syringe Pump - Volume	Using Infusion Pump Analyzer by Comparison Method	5 ml to 50 ml	8.40%
38	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Tidal Volume (VT) / Minute Voulme (MV) - Anesthesia Machine	Using Gas Flow Analyzer by Comparison method	100 ml to 1500 ml	4.1%
39	MEDICAL DEVICES-DISCHARGE EQUIPMENT/DEVICES	Volume - Enteral Feeding Pump	Using Infusion Pump Analyzer by Comparison method	5 ml to 400 ml	6.10%
40	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Machine - Amplitude	Using Vital sign simulator by Simulation Method	0.5 mV to 5.0 mV	4.77%
41	MEDICAL DEVICES-IMAGING/PLOTTERS	ECG Machine - Heart Rate	Using Vital sign simulator by Simulation Method	30 bpm to 300 bpm	4.74%

SCOPE OF ACCREDITATION

Laboratory Name : ROOTS METROLOGY & TESTING LABORATORY, 156, BOMMASANDRA INDUSTRIAL AREA, BOMMASANDRA - JIGANI LINK ROAD, ANEKAL TALUK, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

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42	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Common - Enclosure leakage current NC (Trans illuminator light source, EEG, ECG)	Using Electrical Safety Analyzer by Direct Method	4 µA to 100 µA	0.90 µA
43	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Common - Enclosure leakage current SFC (Trans illuminator light source, EEG, ECG)	Using Electrical Safety Analyzer by Direct Method	4 µA to 500 µA	0.92 µA
44	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Common - Ground Wire Resistance (Trans illuminator light source, EEG, ECG)	Using Electrical Safety Analyzer by Direct Method	0.1 ohm to 2 ohm	9.57%
45	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Common - Patient Lead Leakage Current and Earth Leakage Current (Trans illuminator light source, EEG, ECG)	Using Electrical Safety Analyzer by Direct Method	4 µA to 8 mA	0.91 µA
46	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Common - Voltage (Trans illuminator light source, EEG, ECG)	Using Electrical Safety Analyzer by Direct Method	90 V to 240 V	8.13%

SCOPE OF ACCREDITATION

Laboratory Name : ROOTS METROLOGY & TESTING LABORATORY, 156, BOMMASANDRA INDUSTRIAL AREA, BOMMASANDRA - JIGANI LINK ROAD, ANEKAL TALUK, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

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47	MEDICAL DEVICES-IMAGING/PLOTTERS	Electrical Safety Common- Insulation Test (Trans illuminator light source, EEG, ECG)	Using Electrical Safety Analyzer by Direct Method	0.10 Mohm to 100 Mohm	8.1%
48	MEDICAL DEVICES-IMAGING/PLOTTERS	Fetal Heart Rate (FHR) - Fetal Doppler	Using Fetal Simulator by Direct Method	60 bpm to 240 bpm	4.61%
49	MEDICAL DEVICES-IMAGING/PLOTTERS	OT Light, Examination Light, Slit Lamp	Using Digital Illuminance / Lux Meter by Comparison Method	20000 Lux to 100000 Lux	7.44%
50	MEDICAL DEVICES-IMAGING/PLOTTERS	OT Light, Examination Light,Light Source,Slit Lamp	Using Digital Illuminance / Lux Meter by Comparison Method	100 Lux to 20000 Lux	7.44%
51	MEDICAL DEVICES-IMAGING/PLOTTERS	Trans illuminator Light Source,Endoscopy Unit	Using Digital Illuminance / Lux Meter by Comparison Method	10000 Lux to 100000 Lux	7.44%
52	MEDICAL DEVICES-MONITORING UNIT	Electrical Safety - Voltage - Patient Monitors, Apnea Monitors, Fetal monitors, Therapeutic Stimulator, Hematology Analyzer	Using Electrical Safety Analyzer by Direct Method	90 V to 240 V	7.59%

SCOPE OF ACCREDITATION

Laboratory Name : ROOTS METROLOGY & TESTING LABORATORY, 156, BOMMASANDRA INDUSTRIAL AREA, BOMMASANDRA - JIGANI LINK ROAD, ANEKAL TALUK, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

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53	MEDICAL DEVICES-MONITORING UNIT	Enclosure leakage current NC - Patient Monitors, Apnea Monitors, Fetal monitors, Therapeutic Stimulator, Hematology Analyzer	Using Electrical Safety Analyzer by Direct Method	4 µA to 100 µA	0.90 µA
54	MEDICAL DEVICES-MONITORING UNIT	Enclosure leakage current SFC - Patient Monitors, Apnea Monitors, Fetal monitors, Therapeutic Stimulator, Hematology Analyzer	Using Electrical Safety Analyzer by Direct Method	4 µA to 500 µA	0.92 µA
55	MEDICAL DEVICES-MONITORING UNIT	Fetal Electrocardiograph (fECG) - Fetal Monitor	Using Fetal Simulator by Simulation Method	0.5 mV to 2 mV	3.33%
56	MEDICAL DEVICES-MONITORING UNIT	Fetal Heart Rate (FHR) - Fetal Monitor	Using Fetal Simulator by Simulation Method	60 bpm to 240 bpm	4.61%

SCOPE OF ACCREDITATION

Laboratory Name :	ROOTS METROLOGY & TESTING LABORATORY, 156, BOMMASANDRA INDUSTRIAL AREA, BOMMASANDRA - JIGANI LINK ROAD, ANEKAL TALUK, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA
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57	MEDICAL DEVICES-MONITORING UNIT	Ground Wire Resistance - Patient Monitors, Apnea Monitors, Fetal monitors, Therapeutic Stimulator, Hematology Analyzer	Using Electrical Safety Analyzer by Direct Method	0.1 ohm to 2 ohm	9.57%
58	MEDICAL DEVICES-MONITORING UNIT	Heart Rate - Apnea Monitor	Using Vital Sign Simulator by Simulation Method	30 bpm to 300 bpm	4.66%
59	MEDICAL DEVICES-MONITORING UNIT	Insulation Test - Patient Monitors, Apnea Monitors, Fetal monitors, Therapeutic Stimulator, Hematology Analyzer	Using Electrical Safety Analyzer by Direct Method	0.10 Mohm to 100 Mohm	8.10%
60	MEDICAL DEVICES-MONITORING UNIT	Maternal Electrocardiograph (mECG) - Fetal Monitor	Using Fetal Simulator by Simulation Method	0.5 mV to 2 mV	4.85%
61	MEDICAL DEVICES-MONITORING UNIT	Maternal Heart Rate (MHR) - Fetal Monitor	Using Fetal Simulator by Simulation Method	60 bpm to 160 bpm	2.62%

SCOPE OF ACCREDITATION

Laboratory Name :	ROOTS METROLOGY & TESTING LABORATORY, 156, BOMMASANDRA INDUSTRIAL AREA, BOMMASANDRA - JIGANI LINK ROAD, ANEKAL TALUK, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA
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62	MEDICAL DEVICES-MONITORING UNIT	Patient Lead Leakage Current and Earth Leakage Current - Patient Monitors, Apnea Monitors, Fetal monitors, Therapeutic Stimulator, Hematology Analyzer	Using Electrical Safety Analyzer by Direct Method	4 µA to 8 mA	0.91 µA
63	MEDICAL DEVICES-MONITORING UNIT	Patient Monitors - Heart Rate, Pulse Rate (NIBP Apparatus)	Using Vital sign simulator by Simulation Method	30 bpm to 300 bpm	4.82%
64	MEDICAL DEVICES-MONITORING UNIT	Patient Monitors, NIBP Apparatus - NIBP (Dynamic) Manometer (Systolic and Diastolic)	Using Vital sign simulator by Simulation Method	0 to 300 mmHg	6.02%
65	MEDICAL DEVICES-MONITORING UNIT	Pulse Rate - Patient Monitors	Using Vital Sign Simulator with SpO2 Test Module by Simulation Method	30 bpm to 240 bpm	4.95%
66	MEDICAL DEVICES-MONITORING UNIT	SPO2 - Patient Monitors	Using Vital Sign Simulator with SpO2 Test Module by Simulation Method	70 % to 100 %	6.70%

SCOPE OF ACCREDITATION

Laboratory Name : ROOTS METROLOGY & TESTING LABORATORY, 156, BOMMASANDRA INDUSTRIAL AREA, BOMMASANDRA - JIGANI LINK ROAD, ANEKAL TALUK, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

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67	MEDICAL DEVICES-MONITORING UNIT	Weighing Scale & Balance-Class III and Coarser (Readability:1 g and Coarser)	Using E2 & M1 Class Standard Weights as per OIML R 76	100 mg to 35 kg	7.28g
68	MEDICAL DEVICES-MONITORING UNIT	Weighing Scale & Balance-Class IIII (Readability: 10 g)	Using M1 Class Standard weights as per OIML R 76	500 g to 200 kg	14.66g
69	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Air Flow - Infant Incubator	Using Incubator Analyzer by Comparison Method	0.2 m/s to 2.0 m/s	0.12m/s
70	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - Charge Time	Using Defibrillator / Pacemaker Analyzer by Comparison Method	0 to 15 s	4.01%
71	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - NIBP	Using Vital Sign Simulator by Simulation Method	50 mmHg to 300 mmHg	2.41%

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72	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - Output Energy	Using Defibrillator / Pacemaker Analyzer by Comparison Method	20 Joules to 300 Joules	3.18%
73	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - SpO2 Percentage	Using Vital Sign Simulator with SpO2 Test Module by Simulation Method	70 % to 100 %	6.7%
74	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Defibrillator - Synchronization	Using Defibrillator / Pacemaker Analyzer by Comparison Method	0 to 60 msec	5.5%
75	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Electrical Safety - Insulation Test (Incubator, Defibrillator, Ventilator, Electro Surgical Unit/ Diathermy Machine, Electronic Tourniquet, Dialysis Machine, Patient Warmer, OT Table, Radiant Warmer	Using Electrical Safety Analyzer by Direct Method	0.10 Mohm to 100 Mohm	8.1%

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76	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Electrical Safety Common - Voltage (Incubator, Defibrillator, Ventilator, Electro Surgical Unit/ Diathermy Machine, Electronic Tourniquet, Dialysis Machine, Patient Warmer, OT Table, Radiant Warmer)	Using Electrical Safety Analyzer by Direct Method	90 V to 240 V	7.81%
77	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Electro Surgical Unit / Diathermy machine / Cautry Machine - Output Power	Using Electrosurgical Analyzer by Comparison method	10 W to 300 W	8.56%
78	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Electronic Tourniquet - Pressure	Using Vital Sign Simulator, Stop Watch by Comparison method	0 to 400 mmHg	2.41%
79	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Electronic Tourniquet - Time Interval	Using Stop Watch by Comparison method	1 s to 15 min	1.86s

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Laboratory Name : ROOTS METROLOGY & TESTING LABORATORY, 156, BOMMASANDRA INDUSTRIAL AREA, BOMMASANDRA - JIGANI LINK ROAD, ANEKAL TALUK, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

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80	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Enclosure leakage current NC (Incubator, Defibrillator, Ventilator, Electro Surgical Unit/ Diathermy Machine, Electronic Tourniquet, Dialysis Machine, Patient Warmer, OT Table, Radiant warmer)	Using Electrical Safety Analyzer by Direct Method	4 µA to 100 µA	0.90 µA
81	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Enclosure leakage current SFC - (Incubator, Defibrillator, Ventilator, Electro Surgical Unit/ Diathermy Machine, Electronic Tourniquet, Dialysis Machine, Patient Warmer, OT Table, Radiant warmer)	Using Electrical Safety Analyzer by Direct Method	4 µA to 500 µA	0.92 µA
82	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	External Pace Maker - Pacer Current	Using Defibrillator Analyzer by Comparison Method	8 mA to 100 mA	6.90%

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Laboratory Name : ROOTS METROLOGY & TESTING LABORATORY, 156, BOMMASANDRA INDUSTRIAL AREA, BOMMASANDRA - JIGANI LINK ROAD, ANEKAL TALUK, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

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83	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	External Pacemaker - Pacer Rate	Using Defibrillator Analyzer by Comparison Method	20 ppm to 300 ppm	9.96%
84	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Flow Rate - Dialysis Machine	Using Dialysis Reference Meter by Comparison Method	100 ml/min to 2000 ml/min	2.91%
85	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Ground Wire Resistance (Incubator, Defibrillator, Ventilator, Electro Surgical Unit/ Diathermy Machine, Electronic Tourniquet, Dialysis Machine, Patient Warmer, OT Table, Radiant warmer)	Using Electrical Safety Analyzer by Direct Method	0.1 ohm to 2 ohm	9.57%
86	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Inspiratory Time (Ti), Expiratory Time (Te) for I:E Ratio - Ventilator	Using Gas Flow Analyzer by Comparison method	4:1 to 1:4	4.71%

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Laboratory Name : ROOTS METROLOGY & TESTING LABORATORY, 156, BOMMASANDRA INDUSTRIAL AREA, BOMMASANDRA - JIGANI LINK ROAD, ANEKAL TALUK, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

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Validity 21/10/2023 to 20/10/2025 **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)(±)
87	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Irradiance - Phototherapy	Using Phototherapy Radiometer by Comparison Method	0 to 100 µW/cm2/nm	5.78%
88	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Oxygen Percentage - Ventilator	Using Gas Flow Analyzer by Comparison method	21 % to 100 %	3.83%
89	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Patient Leakage Current, Earth Leakage Current (Incubator, Defibrillator, Ventilator, Electro Surgical Unit, Electronic Tourniquet, Dialysis Machine, Patient Warmer, OT Table, Radiant Warmer)	Using Electrical Safety Analyzer by Direct Method	4 µA to 8 mA	0.91 µA
90	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Pressure - Autoclave	Using Digital Pressure gauge by comparison method	0 to 4.2 bar	1.61%

SCOPE OF ACCREDITATION

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91	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Pressure - Dialysis Machine	Using Dialysis Reference Meter by Comparison Method	0 to 1900 mmHg	5.95mmHg
92	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Relative Humidity - Infant Incubator	Using Incubator Analyzer by Comparison Method	30 %rh to 90 %rh @ 25 °C	4.7%rh
93	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Respiration Rate - Ventilator	Using Gas Flow Analyzer by Comparison method	2 brpm to 150 brpm	9.77%
94	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Sound Level - Infant Incubator @ 1kHz	Using Incubator Analyzer by Comparison Method	30 dB to 120 dB	2.95dB
95	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Temperature - Autoclave	Using RTD Sensor with Indicator by Comparison method	50 °C to 150 °C	0.81°C

SCOPE OF ACCREDITATION

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96	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Temperature - Dialysis Machine	Using Dialysis Reference Meter by Comparison Method	0 °C to 50 °C	0.15°C
97	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Temperature - Incubator	Using RTD Sensor with Indicator by Comparison method	20°C to 150°C	0.81°C
98	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Temperature - Infant Incubator	Using Incubator Analyzer by Comparison Method	25 °C to 40 °C	0.60°C
99	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Temperature - Infant Warmer, Radiant Warmer	Using Incubator Analyzer by Comparison Method	25 °C to 40 °C	0.60°C
100	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Temperature - Patient Warmer	Using RTD Sensor With Indicator by Comparison method	33 °C to 44 °C	0.45°C

SCOPE OF ACCREDITATION

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101	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Tidal Volume (VT) / Minute Volume (MV) - Ventilator	Using Gas Flow Analyzer by Comparison method	100 ml to 1500 ml	4.06%
102	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Time - Dialysis Machine	Using Dialysis Reference Meter by Comparison Method	10 s to 9000 s	1.23s
103	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Ventilator - Peak Inspiratory Pressure (PIP)	Using Gas Flow Analyzer by Comparison method	0 to 145 cmH2O	5.99%
104	MEDICAL DEVICES-PATIENT CONDITIONING / MAINTENANCE	Ventilator - Positive End Expiratory Pressure (PEEP)	Using Gas Flow Analyzer by Comparison method	10 cmH2O to 40 cmH2O	6.14%

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