FEDERATION FOR DEVELOPMENT OF ACCREDITATION SERVICES

118-119, First Floor, Sushant Tower, Sector – 56, Gurugram – 122011, Haryana, India.

CERTIFICATE OF ACCREDITATION

(AS PER ISO/IEC 17025:2017)

This is to attest that

PARASHAR MICRO MEASUREMENT PVT. LTD. (UNIT – II)

J-22, Site-C, Surajpur Industrial Area, UPSIDC,
Greater Noida-201306 (Uttar Pradesh), India

Calibration Laboratory

has demonstrated compliance with ISO/IEC Standard 17025:2017, General requirements for the competence of testing and calibration laboratories and supplementary criteria for Calibration laboratories.

Certificate Number: CL- 130

Issue Date: 12.07.2024 **Valid Until:** 11.07.2026

The certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard and the relevant requirements of FDAS. (for scope of accreditation visit website www. fdasindia.org).

DEVI SARAN TEWARI
Director

FEDERATION FOR DEVELOPMENT OF ACCREDITATION SERVICES

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SCOPE OF ACCREDITATION

(Annexure to Certificate of CL - 130)

Laboratory Name: PARASHAR MICRO MEASUREMENT PVT. LTD. (UNIT-II)
J-22, Site-C, Surajpur Industrial Area, UPSIDC,
Greater Noida-201306 (Uttar Pradesh), India

Validity: 12.07.2024 to 11.07.2026 **Amended on** N/A

S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *

Mechanical Calibration (Laboratory based)

Group: Dimension				
1	Metric Steel Scale	Direct Method by Scale & Tape Calibrator (MSTC)/CP/M/D/24, IS:1481-1970 RA 2019	0 - 2000 mm	0.058mm
2	Metric Steel Tape	Direct Method by Scale & Tape Calibrator (MSTC)/CP/M/D/24, IS:1269(Part-2)-1997 RA 2018	0 – 1000 mm	0.101mm
			>1000 to 3000mm	0.103mm
			>3000 to 5000mm	0.105mm
			>5000 to 10000mm	0.118mm
			>10000 to 20000mm	0.158mm
			>20000 to 30000mm	0.21 mm
			>30000 to 50000mm	0.35mm
3	Woven Metallic & Glass Fiber Tape/ Measuring Tape	Direct Method by Scale & Tape Calibrator (MSTC)/CP/M/D/24, IS:1269(Part-1)-1997 RA 2018	0 – 1000 mm	0.101mm
			>1000 to 3000mm	0.103mm
			>3000 to 5000mm	0.105mm
			>5000 to 10000mm	0.118mm
			>10000 to 20000mm	0.158mm
			>20000 to 30000mm	0.21 mm
			>30000 to 50000mm	0.35mm
4	Pie – Tape	Direct Method by Scale & Tape Calibrator (MSTC)/CP/M/D/24, IS:1269(Part-2)-1997 RA 2018	0 to 5000mm	0.105mm

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *
		Mechanical Calibration (Laboratory based)		
5	Micrometer Head L.C 0.0001 mm	Direct Method by Universal Length Measuring Machine (ULM)/CP/M/D/01, IS:9483-1993 RA 2020	0 – 50 mm	0.00069mm
6	3-Pin wire set	Direct Method by Universal Length Measuring Machine (ULM)/CP/M/D/25, IS: 6311-1978 RA 2020	0.170mm to 6.350mm	0.00030mm
7	Micrometer Setting Rod A) Flat Ended B) Round Ended	Comparison Method Universal Length Measuring Machine (ULM)/CP/M/D/02	25 mm- 100mm 100mm - 225mm	0.00077mm 0.002mm
8	Dial Gauge L.C 0.0001 mm	Direct Method by Universal Length Measuring Machine (ULM)/CP/M/D/03, IS: 2092-1983 RA 2019	0 – 25 mm	0.0003mm
9	Dial Gauge L.C 0.001 mm	Direct Method by Universal Length Measuring Machine (ULM)/CP/M/D/03, IS: 2092-1983 RA 2019	0-50 mm	0.00072mm
10	Dial Gauge L.C 0.01 mm	Direct Method by Universal Length Measuring Machine (ULM)/CP/M/D/03, IS: 2092-1983 RA 2019	0-100 mm	0.0024mm

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *
		Mechanical Calibration (Laboratory based)		
11	Bore Gauge	Direct Method by Universal Length Measuring Machine (ULM)/CP/M/D/04, JIS B 7515 -1982	Upto 2 mm Travel Only	0.00026mm
12	Lever Type Dial Gauge L.C 0.001 mm	Direct Method by Universal Length Measuring Machine (ULM)/CP/M/D/05, IS: 11498 -2023	0 - 0.14 mm	0.00026 mm
13	Lever Type Dial Gauge 0.002 mm	Direct Method by Universal Length Measuring Machine (ULM)/CP/M/D/05, IS: 11498 -2023	0 - 0.28 mm	0.00033 mm
14	Lever Type Dial Gauge 0.01 mm	Direct Method by Universal Length Measuring Machine (ULM)/CP/M/D/05, IS: 11498 -2023	0 - 0.8 mm	0.0012mm
15	Snap Gauge (Plain/Go & NoGo/Dial /Single ended progressive type plate)	Direct Method by Universal Length Measuring Machine (ULM)/CP/M/D/06, IS:7876 -1975 RA 2020	3 to 100 mm	0.00077mm
16	Snap Gauge (Plain/Go & NoGo/Dial /Single ended progressive type plate)	Direct Method by Universal Length Measuring Machine (ULM)/CP/M/D/06, IS:7876 -1975 RA 2020	100 to 225 mm	0.0018mm

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *

Mechanical Calibration (Laboratory based)

17	Measuring Pin and Cylindrical Pin	Direct Method by Universal Length Measuring Machine (ULM)/CP/M/D/07, IS: 11103 -1984 RA 2020	0.01mm to 2 mm	0.0003mm
			2 to 20 mm	0.0003mm
18	Feeler Gauge	Direct Method by Universal Length Measuring Machine (ULM)/CP/M/D/08, IS: 3179 -1990 RA 2020	0.03 to 1 mm	0.00025mm
19	Standard Thickness Foils	Comparison Method by Universal Length Measuring Machine (ULM)/CP/M/D/09	0.01 to 5 mm	0.00030mm
20	Ball Bar & Master	Direct Method by Universal Length Measuring Machine (ULM)/CP/M/D/09	1 to 100 mm	0.00077mm
21	Plain Ring Gauge	Direct Method by Universal Length Measuring Machine (ULM)/CP/M/D/10, IS: 7876 -1975 RA 2020, IS: 3455 - 1985 RA 2020 & IS: 3485 - 1983 RA 2019	4mm - 50 mm	0.00045mm
			50mm - 100 mm	0.00075mm
			100mm - 225 mm	0.00155mm
22	Plain Plug Gauge	Direct Method by Universal Length Measuring Machine (ULM)/CP/M/D/11, IS: 6244-1980 RA 2017	1 to 50 mm	0.00045mm
			50mm - 100 mm	0.00075mm
			100mm - 225 mm	0.0016mm

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *
		Mechanical Calibration (Laboratory based)		
23	Thread Ring Gauge	Direct Method by Universal Length Measuring Machine (ULM)/CP/M/D/12 IS 2334 – 2001 RA 2023, IS 10216 – 1988 RA 2020, Euramet CG10/V – 0.1	4 to 50 mm	0.00043 mm
			50 to 100 mm	0.00075 mm
24	Thread Plug Gauge	Direct Method by Universal Length Measuring Machine (ULM)/CP/M/D/13 IS 2334 – 2001 RA 2023, IS 2334 – 2001 RA 2023, IS 10216 – 1988 RA 2020, Euramet CG10/V – 0.1	1mm to 100mm	0.00075 mm
			100mm to225mm	0.0015 mm
25	Test Sieves	Direct Method by Video Measuring Machine (VMM)/CP/M/D/14, IS: 460 (Part-1,2,3)-2020	0.03mm to 10mm	0.0024mm
26	Test Sieves	Direct Method by Vernier Caliper /CP/M/D/14, IS: 460 (Part-1,2,3)-2020	10mm to 125mm	0.016mm
27	Combination Set & Angle Protractor	Direct Method by Video Measuring Machine (VMM)/Digital Caliper, CP/M/D/15, IS: 4239 - 2023	0 – 90°	7 minutes of Arc

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *
		Mechanical Calibration (Laboratory based)		
28	Bevel Protector	Direct Method by Video Measuring Machine (VMM)/CP/M/D/15, IS: 4239 -2023	0 – 90°	0.8 minutes of Arc
29	Welding Fillet Gauge, Templates, Vickers/Knoop/Rockwell Diamond Cone Indenter/Weld/Hi-Lo Gauge, Bridge cam gauge / Traverse of Cupping machine/ Limit gauge /CD Gauge/ PCD Gauge/JIG Fixtures (2D)/ All Industries Gauge & Templates.	Direct Method by Video Measuring Machine (VMM)/CP/M/D/23 As per specification	Linear: 0.01 to 200 mm	0.003mm
			Angle: 0 - 90°	17.0 Second of Arc
30	Elongation Gauge/Index	Direct Method by Video Measuring Machine (VMM) / CP/M/D/16, IS: 2386-1963 RA 2021	0.01 to 200 mm	0.0025mm

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *
		Mechanical Calibration (Laboratory based)		
31	Flakiness Gauge/Index	Direct Method by Video Measuring Machine (VMM) / CP/M/D/16, IS: 2386-1963 RA 2021	0.01 to 200 mm	0.0025mm
32	Form Gauge	Comparison Method by Video Measuring Machine (VMM) / CP/M/D/18	0.01 to 200 mm	0.0025mm
33	Thread Pitch Gauge	Direct Method by Video Measuring Machine (VMM) / CP/M/D/19, IS: 4211 - 1993 RA 2021	Linear: 0.4mm to 6mm	0.0021mm
			Angle: Up to 60°	17.0 second of Arc
34	Radius Gauge	Direct Method by Video Measuring Machine (VMM)/ CP/M/D/20, IS: 5273 -1969 RA 2019	0.6 to 25 mm	0.0025mm
35	Angle Gauge Set	Direct Method by Video Measuring Machine (VMM)/ CP/M/D/15, IS: 6231 -1971 RA 2019	0 to 90°	16.7 Second of Arc
36	Angular Scale	Direct Method by Video Measuring Machine (VMM)/ CP/M/D/15, IS: 6231 -1971 RA 2019	0 to 90°	6.9 Minutes of Arc

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *

Mechanical Calibration (Laboratory based)

37	Test Finger	Direct Method by Video Measuring Machine (VMM)/ CP/M/D/21, IS: 1401 -2008 RA 2018	Linear: Upto 200 mm	0.0025mm
			Angle: Up to 90°	16.1 Second of Arc
38	Wire Gauge	Direct Method by Video Measuring Machine (VMM)	0.0254 mm to 7.620 mm	0.002mm
39	Glass Scale	Direct Method by Video Measuring Machine (VMM)/ CP/M/D/22, JIS B 7541: 2001	0 - 1mm	0.0053 mm
			0-200 mm	0.0088 mm
		Scale & Tape Calibrator (MSTC)/ CP/M/D/22, JIS B 7541: 2001	>200 - 300 mm	0.0186 mm

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *
		Medical Devices Calibration (Laboratory based)		
Group: Discharge Equipment/Devices				
1	BP Apparatus (Sphygmo-Manometer)			
1.1	NIBP (Non-Invasive Blood Pressure)	IS/IEC: 80601-2-30:2018 by Direct method using Vital Sign Simulator (ProSim-4) CP/BM/02	35/15 (22) mmHg	4.04%
			60/30 (40) mmHg	2.52%
			120/80 (93) mmHg	1.12%
			150/100 (117) mmHg	0.76%
			200/150 (167) mmHg	0.60%
1.2	Pulse Rate		30 to 300 BPM	3.20% to 1.43%
1.3	Leak Test		<2mmHg	0.42 mmHg
1.4	Pressure Relief Test		<330mmHg	1.44 mmHg
2	Electrical Suction Machine/Suction Meter			
2.1	Vacuum	IS 8243-2: 1993 by Direct method using Digital Differential Pressure Gauge CP/BM/07	(-) 0.95 to 0 Bar	0.003 Bar
3	Flow Meter & Humidifier			
3.1	Flow Rate	IS/ISO: 80601-2-12:2023 by Direct method using Gas	1 to 14lpm	4.95% to 3.41%
4	Nebulizer (Electric)			
4.1	Flow Rate	IS/ISO: 80601-2-12:2023 by Direct method using Gas Flow Analyzer CP/BM/06	1 to 14lpm	4.95% to 1.85%

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *
		Medical Devices Calibration (Laboratory based)		
5	Syringe Pump/Infusion Pump/Enternal feeding Pump			
5.1	Flow Rate	IS 13450 (Part-2/sec 24):2019 by Direct method using Infusion Device Analyzer CP/BM/05	10 to 990 ml/hr	9.55% to 0.55%
5.2	Volume		5 to 400 ml	3.69% to 0.79%
5.3	Occlusion Test/Pressure		5 to 40 psi	10.04% to 1.30%
6	Boyles Apparatus			
6.1	Pressure	DKD-R6-1:2016 by Comparison method using Digital Pressure Gauge, CP/BM/07	0-400 Bar	0.03Bar
6.2	Flow Rate	IS/ISO: 80601-2-12:2023 by Direct method using Gas Flow Analyzer CP/BM/06	1 to 300lpm	4.95% to 1.85%
7	CPAP/BiPAP			
7.1	Volume	IS/ISO: 80601-2-12:2023 by Direct method using Gas Flow Analyzer CP/BM/06	0 to 1500ml	3.22% to 2.23%
7.2	Pressure		0 to 10 Bar	0.01 Bar
7.3	O2 Concentration		20 to 100%	3.21%

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *
		Medical Devices Calibration (Laboratory based)		
8	Anesthesia Machine			
8.1	Volume	IS/ISO: 80601-2-13: 2024 by Direct method using Gas Flow Analyzer CP/BM/06	0 to 1500ml	3.22% to 2.23%
8.2	Pressure		0 to 10 Bar	0.01Bar
8.3	O2 Concentration		20 to 100%	3.21%
8.4	VT/MV (Tidal/Minute Volume)		0 to1500 ml	3.22% to 2.23%
8.5	PIP (Peak Inspiratory Pressure)/ MAP (Mean Airway Pressure)/ IPP (Inspiratory Pause Pressure)/ PEEP (Positive end expiratory pressure)		±160 cmH2O	0.15%
8.6	PIF (Peak Inspiratory Flow)/ PEF (Peak Expiratory Flow)		1 to 300lpm	4.95% to 1.85%
9	Electrical Suction Machine/Suction Meter, Nebulizer (Electric), Syringe Pump, Infusion Pump, Enternal Feeding Pump, CPAP, BiPAP, Boyles Apparatus, Anesthesia Machine			
9.1	Ground Wire/Earth Resistance	IS:13450 (Part-1) 2024 by Direct method using Electrical Safety Analyzer, CP/BM/01	0.1 to 2 Ω	3.97%
9.2	Insulation Resistance		0.5 to 100 MΩ	13.01% to 1.71%
9.3	Chassis Leakage		23 to 700µA	8.07% to 1.18%
9.4	Patient Lead Leakage		23 to 700µA	8.07% to 1.18%
9.5	Patient Leakage		10µA to 8mA	20.30% to 1.10%

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *
		Medical Devices Calibration (Laboratory based)		
Group: Patient Conditioning/Maintenance				
10	Autoclave			
10.1	Temperature	IS:2806-1992(Ra-2018) & ITS-90 conversion table by Direct method using Temperature Data Logger CP/BM/08	0-130°C	0.3°C
10.2	Pressure	DKD-R6-1:2016 by Comparison method using Digital Pressure Gauge CP/BM/07	0-40 Bar	0.03Bar
11	Defibrillator			
11.1	Energy Measurement	IS 13450 (Part-2/sec4):2023 by Direct method using Defibrillator Analyzer CP/BM/04	10 to 350 Joules	2.97% to 1.41%
11.2	Charge Time		2 to 90sec	0.31sec to 0.7 sec
11.3	ECG Simulation		30 to 300 BPM	3.13% to 1.42%
12	Ventilator			
12.1	Volume	IS/ISO: 80601-2-12 :2023 by Direct method using Gas Flow Analyzer CP/BM/06	0 to 1500ml	3.22% to 2.23%%
12.2	Pressure		0 to 10 Bar	0.01Bar
12.3	O2 Concentration		20 to 100%	3.21%
12.4	VT (Tidal Volume)		0 to 1500ml	3.64%
12.5	MV (Minute Volume)		0 to 1500ml	3.19%
12.6	PIF (Peak Inspiratory Flow)/ PEF (Peak Expiratory Flow)		1 to 300lpm	1.73%

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *

Medical Devices Calibration (Laboratory based)

12.7	MAP (Mean Airway Pressure)/ IPP (Inspiratory Pause Pressure)		±160 cmH2O	1.44%
12.8	PEEP (Positive end expiratory pressure)		±160 cmH2O	4.01%
12.9	PIP (Peak Inspiratory Pressure)		±160 cmH2O	0.74%
13	Radiant Warmer/Patient Warmer			
13.1	Temperature	IS:2806-1992(Ra-2018) & ITS-90 conversion table by Direct method using Temperature Data Logger CP/BM/08	25 to 42°C	0.3°C
14	Infant Incubator			
14.1	Temperature	IS 13450-2-19:2023 by Direct method using Temperature Data Logger CP/BM/08	25 to 42°C	0.3°C
15	Electronic Tourniquet			
15.1	Time Interval	NIST-960:2012 by Comparison Method using Digital Stopwatch CP/BM/10	1 min. to 60 Min.	0.7 to 1.32 sec

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *
		Medical Devices Calibration (Laboratory based)		
16	OT Light			
16.1	Light Intensity Test	By Comparison method using Digital Lux Meter CP/BM/09	50 to 20,000 LUX	5%
17	Infant Incubator, Autoclave, Defibrillator, Ventilator, Electro-surgical Unit, Diathermy Machine, Cautery Machine, Electronic Tourniquet, Dialysis Machine, Patient Warmer, OT Table, Radiant Warmer, Irradiance meter, Phototherapy Unit, Blood Gas Analyzer, Semi-auto analyzer, Electronic Bed,			
17.1	Ground Wire/Earth Resistance	IS:13450 (Part-1) 2024 by Direct method using Electrical Safety Analyzer, CP/BM/01	0.1 to 2 Ω	3.97%
17.2	Insulation Resistance		0.5 to 100 MΩ	13.01% to 1.71%
17.3	Chassis Leakage		23 to 700µA	8.07 to 1.18%
17.4	Patient Lead Leakage		23 to 700µA	8.07 to 1.18%
17.5	Patient Leakage		10µA to 8mA	20.30% to 1.10%
Group: Monitoring Unit				
18	Patient Monitor			
18.1	NIBP (Non-Invasive Blood Pressure)	ISO/IEC 80601-2-49:2018 by Direct method using Vital Sign Simulator (ProSim-4) & SPO2 Functional Tester (SPOTLIGHT), CP/BM/01, 02 & 03	35/15 (22) mmHg	4.04%
			60/30 (40) mmHg	2.52%
			120/80 (93) mmHg	1.08%
			150/100 (117) mmHg	0.74%
			200/150 (167) mmHg	0.70%
18.2	Respiration		20 to 120 BrPM	13.32% to 12.65%

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *

Medical Devices Calibration (Laboratory based)

18.3	Heart Rate		30-300 BPM	3.34% to 1.43%
18.4	SPO2		70 to 100%	6.06% to 5.74%
19	Pulse Oximeter (Fingertip/Tabletop)			
19.1	SPO2	IEC 60601-2-61:2017 by Direct method using SPO2 Functional Tester (SPOTLIGHT), CP/BM/01 & 03	70 to 100%	6.06% to 5.74%
19.2	Pulse Rate		30 to 240 BPM	12.23% to 3.21%
20	Apnea Monitor, Fetal Monitor, Therapeutic Stimulator, Patient Monitor, Tabletop Pulse Oximeter, Hematology Analyser			
20.1	Ground Wire/Earth Resistance	IS:13450 (Part-1) 2024 by Direct method using Electrical Safety Analyzer, CP/BM/01	0.1 to 2 Ω	2.94%
20.2	Insulation Resistance		0.5 to 100 MΩ	13.01% to 1.71%
20.3	Chassis Leakage		23 to 700µA	1.35%
20.4	Patient Lead Leakage		23 to 700µA	1.35%
20.5	Patient Leakage		10µA to 8mA	1.58%

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *

Medical Devices Calibration (Laboratory based)

Group: Imaging/Plotters				
21	ECG Unit- ECG Heart Rate & ECG Amplitude			
21.1	ECG Heart Rate	IS/IEC: 80601-2-25:2023 by Direct method using Vital Sign Simulator (ProSim-3)/Defibrillator Analyzer CP/BM/02/04	30-300 BPM	3.34% to 1.43%
21.2	ECG Amplitude		1.0 to 5.0mV	19.9% to 5.11%
22	Transilluminator Light Source, ECG Unit, EEG Unit			
22.1	Ground Wire/Earth Resistance	IS:13450 (Part-1) 2024 by Direct method using Electrical Safety Analyzer, CP/BM/01	0.1 to 2 Ω	3.797%
22.2	Insulation Resistance		0.5 to 100 MΩ	13.01% to 1.71%
22.3	Chassis Leakage		23 to 700µA	8.07 to 1.18%
22.4	Patient Lead Leakage		23 to 700µA	8.07 to 1.18%
22.5	Patient Leakage		10µA to 8mA	20.30% to 1.10%

Himanshu

Dealing Officer

SCOPE OF ACCREDITATION

(Annexure to Certificate of CL - 130)

Laboratory Name: PARASHAR MICRO MEASUREMENT PVT. LTD. (UNIT-II)
J-22, Site-C, Surajpur Industrial Area, UPSIDC,
Greater Noida-201306 (Uttar Pradesh), India

Validity: 12.07.2024 to 11.07.2026 **Amended on** N/A

S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *

Medical Devices Calibration (At Site)

Group: Discharge Equipment/Devices				
1	BP Apparatus (Sphygmo-Manometer)			
1.1	NIBP (Non-Invasive Blood Pressure)	IS/IEC: 80601-2-30:2018 by Direct method using Vital Sign Simulator (ProSim-4) CP/BM/02	35/15 (22) mmHg	4.04%
			60/30 (40) mmHg	2.52%
			120/80 (93) mmHg	1.12%
			150/100 (117) mmHg	0.76%
			200/150 (167) mmHg	0.60%
1.2	Pulse Rate		30 to 300 BPM	3.20% to 1.43%
1.3	Leak Test		<2mmHg	0.42 mmHg
1.4	Pressure Relief Test		<330mmHg	1.44 mmHg
2	Electrical Suction Machine/Suction Meter			
2.1	Vacuum	IS 8243-2: 1993 by Direct method using Digital Differential Pressure Gauge CP/BM/07	(-) 0.95 to 0 Bar	0.003 Bar
3	Flow Meter & Humidifier			
3.1	Flow Rate	IS/ISO: 80601-2-12:2023 by Direct method using Gas	1 to 14lpm	4.95% to 3.41%
4	Nebulizer (Electric)			
4.1	Flow Rate	IS/ISO: 80601-2-12:2023 by Direct method using Gas Flow Analyzer CP/BM/06	1 to 14lpm	4.95% to 1.85%

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *
		Medical Devices Calibration (At Site)		
5	Syringe Pump/Infusion Pump/Enternal feeding Pump			
5.1	Flow Rate	IS 13450 (Part-2/sec 24):2019 by Direct method using Infusion Device Analyzer CP/BM/05	10 to 990 ml/hr	9.55% to 0.55%
5.2	Volume		5 to 400 ml	3.69% to 0.79%
5.3	Occlusion Test/Pressure		5 to 40 psi	10.04% to 1.30%
6	Boyles Apparatus			
6.1	Pressure	DKD-R6-1:2016 by Comparison method using Digital Pressure Gauge, CP/BM/07	0-400 Bar	0.03Bar
6.2	Flow Rate	IS/ISO: 80601-2-12:2023 by Direct method using Gas Flow Analyzer CP/BM/06	1 to 300lpm	4.95% to 1.85%
7	CPAP/BiPAP			
7.1	Volume	IS/ISO: 80601-2-12:2023 by Direct method using Gas Flow Analyzer CP/BM/06 Flow Analyzer CP/BM/06	0 to 1500ml	3.22% to 2.23%
7.2	Pressure		0 to 10 Bar	0.02 Bar
7.3	O2 Concentration:		20 to 100%	3.21%

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *

Medical Devices Calibration (At Site)

8	Anesthesia Machine			
8.1	Volume	IS/ISO: 80601-2-13: 2024 by Direct method using Gas Flow Analyzer CP/BM/06	0 to 1500ml	3.22% to 2.23%
8.2	Pressure		0 to 10 Bar	0.01Bar
8.3	O2 Concentration		20 to 100%	3.21%
8.4	VT/MV (Tidal/Minute Volume)		0 to1500 ml	3.22% to 2.23%
8.5	PIP (Peak Inspiratory Pressure)/ MAP (Mean Airway Pressure)/ IPP (Inspiratory Pause Pressure)/ PEEP (Positive end expiratory pressure)		±160 cmH2O	0.15%
8.6	PIF (Peak Inspiratory Flow)/ PEF (Peak Expiratory Flow)		1 to 300lpm	4.95% to 1.85%
9	Electrical Suction Machine/Suction Meter, Nebulizer (Electric), Syringe Pump, Infusion Pump, Enternal Feeding Pump, CPAP, BiPAP, Boyles Apparatus, Anesthesia Machine			
9.1	Ground Wire/Earth Resistance	IS:13450 (Part-1) 2024 by Direct method using Electrical Safety Analyzer, CP/BM/01	0.1 to 2 Ω	3.97%
9.2	Insulation Resistance		0.5 to 100 MΩ	13.01% to 1.71%
9.3	Chassis Leakage		23 to 700µA	8.07% to 1.18%
9.4	Patient Lead Leakage		23 to 700µA	8.07% to 1.18%
9.5	Patient Leakage		10µA to 8mA	20.30% to 1.10%

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *
		Medical Devices Calibration (At Site)		
Group: Patient Conditioning/Maintenance				
10	Autoclave			
10.1	Temperature	IS:2806-1992(Ra-2018) & ITS-90 conversion table by Direct method using Temperature Data Logger CP/BM/08	0-130°C	0.3°C
10.2	Pressure	DKD-R6-1:2016 by Comparison method using Digital Pressure Gauge CP/BM/07	0-40 Bar	0.03Bar
11	Defibrillator			
11.1	Energy Measurement	IS 13450 (Part-2/sec4):2023 by Direct method using Defibrillator Analyzer CP/BM/04	10 to 350 Joules	2.97% to 1.41%
11.2	Charge Time		2 to 90sec	0.31sec to 0.7 sec
11.3	ECG Simulation		30 to 300 BPM	3.13% to 1.42%
12	Ventilator			
12.1	Volume	IS/ISO: 80601-2-12 :2023 by Direct method using Gas Flow Analyzer CP/BM/06	0 to 1500ml	3.22% to 2.23%%
12.2	Pressure		0 to 10 Bar	0.01Bar
12.3	O2 Concentration		20 to 100%	3.21%
12.4	VT (Tidal Volume)		0 to 1500ml	3.64%
12.5	MV (Minute Volume)		0 to 1500ml	3.19%
12.6	PIF (Peak Inspiratory Flow)/ PEF (Peak Expiratory Flow)		1 to 300lpm	1.73%

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *

Medical Devices Calibration (At Site)

12.7	MAP (Mean Airway Pressure)/ IPP (Inspiratory Pause Pressure)		±160 cmH2O	1.44%
12.8	PEEP (Positive end expiratory pressure)		±160 cmH2O	4.01%
12.9	PIP (Peak Inspiratory Pressure)		±160 cmH2O	0.74%
13	Radiant Warmer/Patient Warmer			
13.1	Temperature	IS:2806-1992(Ra-2018) & ITS-90 conversion table by Direct method using Temperature Data Logger CP/BM/08	25 to 42°C	0.3°C
14	Infant Incubator			
14.1	Temperature	IS 13450-2-19:2023 by Direct method using Temperature Data Logger CP/BM/08	25 to 42°C	0.3°C
15	Electronic Tourniquet			
15.1	Time Interval	NIST-960:2012 by Comparison Method using Digital Stopwatch CP/BM/10	1 min. to 60 Min.	0.7 to 1.32 sec

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *
		Medical Devices Calibration (At Site)		
16	OT Light			
16.1	Light Intensity Test	By Comparison method using Digital Lux Meter CP/BM/09	50 to 20,000 LUX	5%
17	Infant Incubator, Autoclave, Defibrillator, Ventilator, Electro-surgical Unit, Diathermy Machine, Cautery Machine, Electronic Tourniquet, Dialysis Machine, Patient Warmer, OT Table, Radiant Warmer, Irradiance meter, Phototherapy Unit, Blood Gas Analyzer, Semi-auto analyzer, Electronic Bed,			
17.1	Ground Wire/Earth Resistance	IS:13450 (Part-1) 2024 by Direct method using Electrical Safety Analyzer, CP/BM/01	0.1 to 2 Ω	3.97%
17.2	Insulation Resistance		0.5 to 100 MΩ	13.01% to 1.71%
17.3	Chassis Leakage		23 to 700µA	8.07 to 1.18%
17.4	Patient Lead Leakage		23 to 700µA	8.07 to 1.18%
17.5	Patient Leakage		10µA to 8mA	20.30% to 1.10%
Group: Monitoring Unit				
18	Patient Monitor			
18.1	NIBP (Non-Invasive Blood Pressure)	ISO/IEC 80601-2-49:2018 by Direct method using Vital Sign Simulator (ProSim-4) & SPO2 Functional Tester (SPOTLIGHT), CP/BM/01, 02 & 03	35/15 (22) mmHg	4.04%
			60/30 (40) mmHg	2.52%
			120/80 (93) mmHg	1.08%
			150/100 (117) mmHg	0.74%
			200/150 (167) mmHg	0.70%
18.2	Respiration		20 to 120 BrPM	13.32% to 12.65%

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *

Medical Devices Calibration (At Site)

18.3	Heart Rate		30-300 BPM	3.34% to 1.43%
18.4	SPO2		70 to 100%	6.06% to 5.74%
19	Pulse Oximeter (Fingertip/Tabletop)			
19.1	SPO2	IEC 60601-2-61:2017 by Direct method using SPO2 Functional Tester (SPOTLIGHT), CP/BM/01 & 03	70 to 100%	6.06% to 5.74%
19.2	Pulse Rate		30 to 240 BPM	12.23% to 3.21%
20	Apnea Monitor, Fetal Monitor, Therapeutic Stimulator, Patient Monitor, Tabletop Pulse Oximeter, Hematology Analyser			
20.1	Ground Wire/Earth Resistance	IS:13450 (Part-1) 2024 by Direct method using Electrical Safety Analyzer, CP/BM/01	0.1 to 2 Ω	2.94%
20.2	Insulation Resistance		0.5 to 100 MΩ	13.01% to 1.71%
20.3	Chassis Leakage		23 to 700µA	1.35%
20.4	Patient Lead Leakage		23 to 700µA	1.35%
20.5	Patient Leakage		10µA to 8mA	1.58%

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S.No.	Parameter	Calibration Method/ Procedure & Equipment used as Reference Standard	Range	Uncertainty in Measurement (±) *
		Medical Devices Calibration (At Site)		
Group: Imaging/Plotters				
21	ECG Unit- ECG Heart Rate & ECG Amplitude			
21.1	ECG Heart Rate	IS/IEC: 80601-2-25:2023 by Direct method using Vital Sign Simulator (ProSim-3)/Defibrillator Analyzer CP/BM/02/04	30-300 BPM	3.34% to 1.43%
21.2	ECG Amplitude		1.0 to 5.0mV	19.9% to 5.11%
22	Trans illuminator Light Source, ECG Unit, EEG Unit			
22.1	Ground Wire/Earth Resistance	IS:13450 (Part-1) 2024 by Direct method using Electrical Safety Analyzer, CP/BM/01	0.1 to 2 Ω	3.797%
22.2	Insulation Resistance		0.5 to 100 MΩ	13.01% to 1.71%
22.3	Chassis Leakage		23 to 700µA	8.07 to 1.18%
22.4	Patient Lead Leakage		23 to 700µA	8.07 to 1.18%
22.5	Patient Leakage		10µA to 8mA	20.30% to 1.10%

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