CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

BITS BIOMEDICAL INC.
Unit G-H RLI Bldg 3, Southpoint Subd.
Laguna PHILIPPINES

Fulfills the requirements of

ISO/IEC 17025:2017

AND

ANSI/NCSL Z540-1-1994 (R2002)

In the fields of

CALIBRATION and TESTING

This certificate is valid only when accompanied by a current scope of accreditation document.
The current scope of accreditation can be verified at www.anab.org.

Jason Stine, Vice President

Expiry Date: 10 July 2027

Certificate Number: ACT-3400

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

AND

ANSI/NCSL Z540-1-1994 (R2002)

BITS BIOMEDICAL, INC.

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CALIBRATION AND TESTING

ISO/IEC 17025 Accreditation Granted: **10 July 2025**

Certificate Number: **ACT-3400** Certificate Expiry Date: **10 July 2027**

Acoustics and Vibration

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Sound Level - Measure [1] Frequency at 1 kHz	(94 to 114) dB	1.7 dB	Direct Measure Using Sound Level Meter
Sound Level - Measure (Infant Incubator) [1] Frequency at 1 kHz	(74 to 94) dB	5.7 dB	Direct Measure Using Incubator Analyzer
Sound Level Meters [1] Frequency at 1 kHz	(94 to 114) dB	0.62 dB	Direct Comparison to a Sound Level Calibrator

Chemical Quantities

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Conductivity Measuring Equipment [5] (Reference Value at 25 °C)	2 µmhos/cm 10 µmhos/cm 100 µmhos/cm 1 200 µmhos/cm 10 000 µmhos/cm 100 000 µmhos/cm	0.2 µmhos/cm 0.2 µmhos/cm 1 µmhos/cm 7 µmhos/cm 44 µmhos/cm 413 µmhos/cm	Comparison to Conductivity Standard Solutions
Conductivity – Measure (Dialysis Machines) [1]	(1 to 100) mS/cm	0.5 mS/cm	Direct Comparison using a Conductivity Module / Dialysis Meter
pH Meter – Measuring Equipment [5] (Reference Value at 25 °C)	4.01 pH 7 pH 10.01 pH	0.02 pH 0.02 pH 0.03 pH	Comparison to pH Standard Solutions
Oxygen Analyzers	20.9 % Concentration 100 % Concentration	1 % Concentration 1.5 % Concentration	Comparison to Standard Calibration Gases
Oxygen Concentrations Measure of Mechanical Ventilator (FIO_2) [1]	(8.0 to 21) % Concentration	1.6 % Concentration	Direct Measure Using a Gas Flow Analyzer

Electrical – DC/Low Frequency

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
AC Voltage (ECG Amplitude) at 1 kHz	100 mV to 10 V	5.5 % of reading	Direct Comparison to a Low Noise Amplifier, Oscilloscope
AC Voltage – Measure [1] (60 Hz)	(110 to 240) V	0.5 % of reading	Direct Comparison to a Digital Multimeter
Radiographic – Tube Voltage [1]	(40 to 150) kVp	3 % of reading	Direct Measure Using a X-Ray Meter
Radiographic – Exposure Linearity [1]	(250 to 2500) mR	6.5 % of reading	Direct Measure Using a X-Ray Meter
Energy – Defibrillator Analyzer [1, 3] (Biphasic & Monophasic)	(1 to 360) Joules	6 % of reading	Direct Comparison to a High Voltage Differential Probe, Oscilloscope
Energy – Defibrillator Unit [1,3] (Biphasic & Monophasic)	(1 to 50) Joules (50 to 150) Joules (150 to 360) Joules	7 % of reading 3.5 % of reading 2 % of reading	Direct Comparison to a Defibrillator Analyzer

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Electrical – DC/Low Frequency

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Power/Electrosurgical Unit [1,3] (Cut and Coag)	(1 to 300) W	2.3 % of reading	Direct Comparison to a Electrosurgical Unit Analyzer
Power/Electrosurgical Analyzer [1,3]	(1 to 300) W	1.3 % of reading	Direct Comparison to a Differential Probe, Oscilloscope, Multimeter
Resistance – Generate [1]	(0.1 to 1) Ω (1 to 100 000) Ω	6 % of reading 1.2 % of reading	Direct Comparison Using a Decade Resistance Box
Resistance – Measure [1]	(0 to 100) Ω 100 Ω to 1 kΩ (1 to 10) kΩ (10 to 100) kΩ 100 kΩ to 1 MΩ (1 to 10) MΩ (10 to 100) MΩ	165 µΩ/Ω 130 µΩ/Ω 130 µΩ/Ω 130 µΩ/Ω 130 µΩ/Ω 475 µΩ/Ω 10 mΩ/Ω	Direct Measure Using a Digital Multimeter

Mass and Mass Related

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Scales and Balances [1,4]	Up to 10 g Up to 100 g (100 to 200) g (200 to 300) g (300 to 1 000) g (1 000 to 3 000) g (3 000 to 6 000) g 8 000 g to 10 kg Up to 50 kg Up to 100 kg Up to 150 kg	0.031 mg 0.16 mg 0.30 mg 0.47 mg 3 mg 9 mg 18 mg 30 mg 160 mg 320 mg 320 mg	Standard Weights
Scales and Balances [1,4]	(150 to 300) kg	0.85 g	Single Substitution Comparison to Standard Weights
Mass (Weight)	(1 to 500) mg 500 mg to 5 g (5 to 100) g 100 g to 50 kg	28 µg 57 µg 1.2 µg/g + 59 µg 1.8 µg/g	Comparison to Standard Weights, Balance

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Mass and Mass Related

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Pipette	(1 to 500) µL (500 to 2 000) µL (2 000 to 5 000) µL (5 000 to 10 000) µL	0.15 µL 3.6 µL 0.85 µL 1.7 µL	Gravimetric Method, Comparison to Analytical Scale, Standard Weights
Flow Rate Measure – Oxygen [1]	(1 to 20) L/min (1 to 300) L/min	5 % of reading 2.8 % of reading	Direct Measure Using a Flow Meter Analyzer
Flow Rate – Liquid [1] Infusion Devices	(1 to 1 000) mL/hr	1.2 % of reading	Direct Measure Using a Infusion Device Analyzer
Volume [1] Infusion Devices	(1 to 400) mL (400 to 1 000) mL	2.5 % of reading 1.3 % of reading	Direct Measure Using a Infusion Device Analyzer
Air Velocity-Measure [1]	(0.3 to 7.5) m/s (7.5 to 15) m/s (15 to 22.5) m/s (22.5 to 30) m/s	0.8 m/s 2.5 m/s 3.6 m/s 4.6 m/s	Direct Measure Using an Anemometer
Pressure Gages [1] (Pneumatic)	(0 to 1 500) psi (1 500 to 5 000) psi	0.2 % of reading 0.08 % of reading	Direct Comparison to a Digital Pressure Gage
Pressure/Blood Pressure Cuff [1] (Pneumatic)	(0 to 100) mmHg (100 to 150) mmHg (150 to 200) mmHg (200 to 250) mmHg (250 to 300) mmHg	1.2 mmHg 1.3 mmHg 1.5 mmHg 1.7 mmHg 1.9 mmHg	Direct Comparison to a Pressure NIBP Simulator
Non-invasive Blood Pressure Monitoring Devices [1] (Pneumatic)	(0 to 100) mmHg (100 to 150) mmHg	1.2 mmHg 1.3 mmHg	Direct Measure to a Pressure NIBP Simulator
Vacuum Measure (Dialysis Machine) [1]	(0 to -50) mmHg (-50 to -100) mmHg (-100 to -200) mmHg (-200 to -300) mmHg (-300 to -400) mmHg (-400 to -500) mmHg	1.6 mmHg 1.8 mmHg 2.3 mmHg 2.9 mmHg 3.4 mmHg 4 mmHg	Direct Comparison using a Pressure Module / Dialysis Meter
Vacuum - Measure [1]	(-15 to 0) psi	0.013 psi	Direct Comparison to a Pressure Standard
Tidal Volume Measure of Mechanical Ventilator [1]	(100 to 1 000) mL	1.3 % of reading	Direct Measure Using a Gas Flow Analyzer

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Photometry and Radiometry

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Irradiance – Measure (Therapeutic Luminaires) [1]	(50 to 2 000) µW/cm²	6 % of reading	Direct Comparison to a Radiometer
Illuminance Measuring Equipment	Up to 90 000 lux	4.2 % of reading	Direct Comparison to a Light Meter
Illuminance – Measure (Examination Luminaires) [1]	Up to 90 000 lux	4.2 % of reading	Direct Measure Using a Light Meter

Thermodynamic

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Relative Humidity – Mapping for incubators [1]	(10 to 50) %RH (50 to 90) %RH	0.95 %RH 2.6 %RH	Direct Measure Using an Incubator Analyzer
Temperature Enclosure (Mapping) [1]	(0 to 140) °C	0.25 °C	Comparison to Datalogger with RTD/ Thermocouple Probe
Temperature Mapping for Incubators [1]	(0 to 50) °C	0.5 °C	Direct Measure Using an Incubator Analyzer
Body Temperature Thermometers [1]	(36 to 41) °C	0.5 °C	Comparison to a tympanic Calibrator
Infrared Thermometer [1]	(30 to 50) °C	0.59 °C	Comparison to Blackbody Source (flat plate) $\varepsilon = 0.97$, $\lambda = (8 \text{ to } 14)$ µm

Time and Frequency

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Timer, and Time Measure [1]	Up to 9 hr	6 s	Direct Measure Using a Stopwatch
Stopwatch, Timer, and Time Measurement [1]	Up to 24 hr	350 ms	Totalize Method Using Universal Counter and Function Generator

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Time and Frequency

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Inspiratory & Expiratory Time Measure of Mechanical Ventilator [1]	(0.5 to 1.5) sec	250 ms	Direct Measure Using a Gas Flow Analyzer
Heart Rate – Source [1,2] Fetal Doppler and Fetal Monitoring Devices	(30 to 240) BPM	2.4 % of reading	Direct Comparison to a Fetal Simulator
Heart Rate – Source [1,2] Patient Monitoring Equipment	(30 to 300) BPM	2.3 % of reading	Direct Comparison to a Patient Simulator
Heart Rate – Measure (Patient Simulators) [1,2]	(30 to 300) BPM	0.3 BPM	Direct Comparison to an Oscilloscope
Respiration Rate Measure of Mechanical Ventilator [1]	(10 to 100) BrPM	2.5 % of reading	Direct Measure Using a Gas Flow Analyzer
Tachometers [1] Non-Contact	(60 to 99 999) rpm	2.1 rpm	Direct Comparison to a Stroboscope
Tachometers Contact	(500 to 3 000) rpm	2.5 rpm	Direct Comparison to a Tachometer
Rotational Speed Measure[1] (Centrifuges)	(60 to 15 000) rpm (15 000 to 30 000) rpm (30 000 to 99 999) rpm	1.8 rpm 5 rpm 8 rpm	Direct Measure Using a Non-Contact Tachometer

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TESTING

Electrical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Ground Resistance, Leakage Current	IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Medical electrical equipment	Electrical Safety Analyzer

Environmental

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Inflow Air Velocity, Down Flow Air Velocity, Light Intensity, Noise Level Test	NSF/ANSI N49: Biosafety Cabinetry: Design, Construction, Performance, and Field Certification (Annex N)	Biological Safety Cabinet Test	Anemometer, Light Meter, Sound Level Meter

Calibration and Measurement Capability (CMC) is expressed in terms of the measurement parameter, measurement range, expanded uncertainty of measurement and reference standard, method, and/or equipment. The expanded uncertainty of measurement is expressed as the standard uncertainty of the measurement multiplied by a coverage factor of 2 (k=2), corresponding to a confidence level of approximately 95%.

Notes:

1. On-site calibration service is available for this parameter, since on-site conditions are typically more variable than those in the laboratory, larger measurement uncertainties are expected on-site than what is reported on the accredited scope.
2. BPM = Beats Per Minute, BrPM = Breath Rate Per Minute, f = frequency, P = power, R = resolution (or readability) of the unit under test, t = time in seconds, rpm = revolutions per minute
3. The reported value represents the final computed result after signal processing, which may include amplification or other adjustments
4. The uncertainties for scales and balances is highly dependent upon the resolution of the unit under test. The uncertainties presented here do not include the resolution of the unit under test. The resolution will be included in the reported measurement uncertainty at the time of calibration.
5. The values of the solutions reflected in this scope of accreditation are the approximate reference value at a reference temperature of 25 °C as taken from the certificate of accreditation and will vary with change in temperature.

Jason Stine, Vice President

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