



# CERTIFICATE OF ACCREDITATION

## The ANSI National Accreditation Board

Hereby attests that

**Sistagrosa S.A.**  
**Cdla Guayaquil, Av. Victor H. Sicuret P. Mz11,**  
**S4; Entre Emilio Soro Lenti y Enma E. Ortiz Bermeo**  
**Guayaquil, Ecuador**

Fulfills the requirements of

**ISO/IEC 17025:2017**

In the field of

**CALIBRATION**

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](http://www.anab.org).

Jason Stine, Vice President

Expiry Date: 02 October 2024  
Certificate Number: AC-2622



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**

**SISTAGROSA S.A.**

Cdla Guayaquil, Av. Victor H. Sicuret P. Mz11, S4; Entre Emilio Soro  
Lenti y Enma E. Ortiz Bermeo  
Guayaquil, Ecuador

Víctor Ernesto Pineda Gonzalez Phone: (011) 59 34 2 269 2375

[sistagrosa@sistagrosa.com](mailto:sistagrosa@sistagrosa.com)

[www.sistagrosa.com](http://www.sistagrosa.com)

**CALIBRATION**

Valid to: **October 2, 2024**

Certificate Number: **AC-2622**

**Acoustics and Vibration**

<b>Parameter/Equipment</b>	<b>Range</b>	<b>Expanded Uncertainty of Measurement (+/-)</b>	<b>Reference Standard, Method, and/or Equipment</b>
Sound pressure Level (Air conduction) Reference (70 dB) <sup>1,2</sup>	(77 to 115) dB HL (125 to 8 000) Hz	(0.092 + 0.001 2X) dB	Internal Procedure PEC.SIS.17; Portable Audiometer Calibration System AEC201 Ear Simulator for 824, Larson Davies
Sound pressure Level (Air conduction) Reference (0 dB) <sup>1,2</sup>	(7 to 45.9) dB HL (125 to 8 000) Hz	(0.014 + 0.003 7X) dB	Internal Procedure PEC.SIS.17; Portable Audiometer Calibration System AEC201 Ear Simulator for 824, Larson Davies
Sound Pressure Level (Bone conduction) Reference (20 dB and 40 dB) <sup>1,2</sup>	(51 to 88) dB HL (250 to 8 000) Hz	(0.17 + 0.000 3X) dB	Internal Procedure PEC.SIS.17; Portable Audiometer Calibration System AEC201whit AMC493B Ear Simulator for 824 Larson Davies



ANSI National Accreditation Board

**Chemical Quantities**

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Breathalyzer Ethanol Weight per Volume of Vapor @ 34°C <sup>1,2</sup>	(0.1 to 0.48) mg/L	(0.001 6 + 0.011X) mg/L	Internal Procedure PEC.SIS.50; Alcohol Accredited Solutions

**Electrical – DC/Low Frequency**

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Energy Monophasic / Defibrillator <sup>1,2</sup>	(15 to 360) J	(0.31 + 0.013X) J	Internal Procedure PEC.SIS.03; Defibrillator/AED Tester, External Pacer Analyzer Fluke Impulse 7000DP
Energy Biphasic / Defibrillator <sup>1,2</sup>	(15 to 175) J	(0.4 + 0.018X) J	Internal Procedure PEC.SIS.03; Defibrillator/AED Tester, External Pacer Analyzer Fluke Impulse 7000DP
Power / Electrosurgical <sup>1,2</sup>	(5 to 300) W at 200 Ω at 300 Ω at 400 Ω at 500 Ω	(1.2 + 0.053X) W (1.1 + 0.053X) W (1.3 + 0.053X) W (1.3 + 0.053X) W	Internal Procedure PEC.SIS.05; Electrosurgery Analyzer Fluke QA ES II
DC Power Measurement Analyzers Load Resistance <sup>1,2</sup>	(50 to 5 200) Ω	(1.292 + 0.001 4X) Ω	Internal Procedure PEC.SIS.30; 5.5 Digit Multimeter Agilent U3402A
Low Frequency Power Measurement <sup>1,2</sup>	(5 to 300) W	(0.372 + 0.002 7X) W	Internal Procedure PEC.SIS.30; 8.5 Digit Multimeter Agilent 3458A
Low Frequency Energy Analyzers <sup>2</sup>	(2 to 360) J	(0.383 + 0.034X) J	Internal Procedure PEC.SIS.22; 5.5 Digit Multimeter Agilent U3402A, Digital Oscilloscope Uni-T UTD2202CE

**Mass and Mass Related**

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Flow/Infusion Pump <sup>1,2</sup>	(16 to 200) ml/hr	$(1.6 + 0.009X)$ ml/hr	Internal Procedure PEC.SIS.01; Infusion Pump Analyzer IDA 4 Plus
Flow Infusion Analyzer <sup>1,2</sup>	(100 to 500) ml/hr	0.000 04 ml/hr	Internal Procedure PEC.SIS.33; Gravimetric Method using Analytical Scale Sartorius
Pressure Gauges <sup>1,2</sup>	Up to 3 500 psi	$(1.9 + 0.000 1X)$ psi	Internal Procedure PEC.SIS.42; Advanced Digital Pressure Gauge HSIN685
Pressure/ Blood Pressure Cuff <sup>1,2</sup>	Up to 300 mmHg	$(0.65 + 0.002 2X)$ mmHg	Internal Procedure PEC.SIS.20; Digital Pressure Gauge ADDITEL ADT681-02- GP5-PSI-N, Vital Signs Patient Simulator Fluke PROSIM 8
Non-Invasive Blood Pressure /Multi-parameter Monitor (Electrical Simulation) <sup>1,2</sup>	(30 to 150) mmHg	$(0.5 + 0.007 4X)$ mmHg	Internal Procedure PEC.SIS.21; Vital Signs Patient Simulator Fluke PROSIM 8
Invasive Blood Pressure / Multi-parameter Monitor (Electrical Simulation) <sup>1,2</sup>	Up to 120 mmHg	$(1.2 + 0.011X)$ mmHg	Internal Procedure PEC.SIS.13; Vital Signs Patient Simulator Fluke PROSIM 8
Non-invasive Pressure Simulator <sup>1,2</sup>	Systolic (60 to 100) mmHg (120 to 150) mmHg Diastolic (30 to 70) mmHg (80 to 110) mmHg Pressure Meter Up to 290 mmHg	$(0.095 + 0.000 08X)$ mmHg $(0.086 + 0.000 1X)$ mmHg $(0.092 + 0.000 1X)$ mmHg $(0.097 + 0.000 06X)$ mmHg 0.011 mmHg	Internal Procedure PEC.SIS.28; Digital Pressure Gauge ADDITEL ADT681-02- GP5-PSI-N, Recorder JUMO LOGOSCREEN
Airway Pressure/Pulmonary Ventilator-Anesthesia Machines <sup>1,2</sup>	(-100 to 100) cmH <sub>2</sub> O	$(0.083 + 0.006 3X)$ cmH <sub>2</sub> O	Internal Procedure PEC.SIS.18; Gas Flow Analyzer Fluke VT900

**Mass and Mass Related**

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Airway Flow/Pulmonary Ventilator-Anesthesia Machines <sup>1,2</sup>	(0.5 to 100) slpm	$(0.008 + 0.02X)$ slpm	Internal Procedure PEC.SIS.18; Gas Flow Analyzer Fluke VT900
Airway Spirometry Volume <sup>1,2</sup>	(1 to 3) l	$(0.2 + 0.000 3X)$ l	Internal Procedure PEC.SIS.07; Gas Flow Analyzer Fluke VT900
Balances and Scales Medical (platform) Adult and Pediatric <sup>1,3</sup>	(100 to 5 000) g (5 to 260) kg	17 $\mu$ g 9.3 g	OIML Class F1 weights, OIML Class M1 weights, and Internal Procedure PEC.SIS.31 utilized in the calibration of the weighing system.

**Thermodynamic**

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Temperature/ Infant Incubator <sup>1</sup>	(25 to 40) °C	0.77 °C	Internal Procedure PEC.SIS.14; Incubator Analyzer Fluke INCU
Temperature/Isothermal Media <sup>1,2</sup>	(-80 to -20) °C (-20 to 0) °C	$(0.42 - 0.000 1X)$ °C $(0.43 + 0.000 5X)$ °C	Internal Procedure PEC.SIS.40; Dry Ice Data Logger YPL-170
Temperature/Temperature Recorders <sup>1</sup>	(-80 to 40) °C	1 °C	Internal Procedure PEC.SIS.44; Thermometer Readout Fluke 1502A, Dry Block Calibrators Tempsens Calsys -100/4

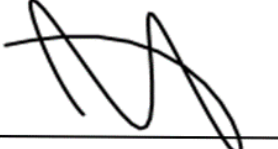
**Time and Frequency**

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Cardiac Rate ECG/Multi-parameter Monitor (Electrical Simulation) <sup>1,2</sup>	(40 to 300) BPM	$(0.022 + 0.011X)$ BPM	Internal Procedure PEC.SIS.11; Vital Signs Patient Simulator Fluke PROSIM 8
Cardiac Rate/Fetal Doppler (Electrical Simulation) <sup>1,2</sup>	(90 to 180) BPM	$(0.6 + 0.0089X)$ BPM	Internal Procedure PEC.SIS.10; Fetal Simulator Fluke PS 320
Respiration Rate-Multi-Parameter Monitor (Electrical Simulation) <sup>1,2</sup>	(20 to 60) BrPM	$(0.033 + 0.06X)$ BrPM	Internal Procedure PEC.SIS.23; Vital Signs Patient Simulator Fluke PROSIM 8
Cardiac Rate/ Electrocardiogram (Electrical Simulation) <sup>1,2</sup>	(40 to 300) BPM	$(0.016X - 0.034)$ BPM	Internal Procedure PEC.SIS.06; Digital Caliper/ Vital Signs Patient Simulator Fluke PROSIM 8
Simulation of Heart Rate <sup>1,2</sup> (40 to 300) BPM	(0.6 to 5) Hz	$(0.0005 + 0.0006X)$ Hz	Internal Procedure PEC.SIS.25; Frequency Reference (Universal Counter) Agilent 53131A
Centrifuge – Rotational Speed <sup>1,2</sup>	(300 to 5 000) rpm	$(0.61 + 0.00007X)$ rpm	Internal Procedure PEC.SIS.37; Digital Tachometer

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.  $X$  = reading of the unit under test; BPM = beats per minute; BrPM = breaths per minute; rpm = revolutions per minute.
3. The CMC for scales and balances is highly dependent upon the resolution of the unit under test. The CMC presented here does not include the resolution of the unit under test. The resolution will be included in the reported measurement uncertainty at the time of calibration.
4. This scope is formatted as part of a single document including Certificate of Accreditation No. AC-2622.



Jason Stine, Vice President