



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

ELICROM CÍA. LTDA.
Cda. Guayaquil, Mz 21 Calle Primera, Solar 10
Guayaquil, Ecuador 090506
Camilo Moreno Phone: 593 4 2282007

MECHANICAL

Valid To: August 31, 2021

Certificate Number: 4286.03

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests:

Measurements: Work Environment

Test	In-house Method	Reference Method
Noise, Sound, Pressure Level	PEE.EL.01	ISO 1996, PART 1 and 2
Temperatures for Thermal Stress, Thermometry	PEE.EL.09	UNE EN ISO 7243
Thermal Comfort	PEE.EL.015	UNE – EN ISO 7730, UNE – EN ISO 7726
Luminosity	PEE.EL.010	NOM – 025; STPS – 2008
Breathable Dust, Gravimetry	PEE.EL.016	NIOSH 0600
Total Particles, Gravimetry	PEE.EL.017	NIOSH 0500
Noise, Noise Dosimetry, Sound Pressure Level	PEE.EL.05	ISO 9612

Measurements: Hand-arm

Test	In-house Method	Reference Method
Vibration	PEE.EL.08	UNE – EN ISO 5349-1, UNE – EN ISO 5349-2

Measurements: Whole Body

<u>Test</u>	<u>In-house Method</u>	<u>Reference Method</u>
Vibration in the Whole Body	PEE.EL.011	UNE – ISO 2631-1

Measurements: Buildings

<u>Test</u>	<u>In-house Method</u>	<u>Reference Method</u>
Vibration	PEE.EL.014	UNE – ISO 2631-1, UNE – ISO 2631-2

Measurements in the Field: Flow Cabinets, Extraction Cabins, Laminar Flow Modules, and Sterile Rooms

<u>Test</u>	<u>In-house Method</u>	<u>Reference Method</u>
Filter Integrity ¹	PEV.EL.02	ISO 14644-3, Item B.6.2.6
Concentration and Particle Size ¹	PEV.EL.02	ISO 14644-1, Annex B and C
Air Flow Laminarity Size ¹	PEV.EL.02	ISO 14644-4, Ítem B. 4.2.2
Display of Air Flow Standard Direction ¹	PEV.EL.02	ISO 14644-3, Ítem 4.2.5, B 7.3.2
Lighting Intensity	PEV.EL.02	ISO 14644, NSF/ANSI 49-2018
Sound Level	PEV.EL.02	ISO 14644, NSF/ANSI 49-2018

Measurements in the Field: Sterile Rooms and Premises with Controlled Environments

<u>Test</u>	<u>In-house Method</u>	<u>Reference Method</u>
Air Flow Rate, Supply and Extraction ¹	PEV.EL.02	ISO 14644-3, Ítem B. 4.3.2
Differential Pressure ¹	PEV.EL.02	ISO 14644-3, Ítem B. 5.2
Thermal Profile ¹	PEV.EL.02	ISO 14644-3, Ítem B 8.2.1 B 9.2

Measurements in the Field: Stability Rooms, Warehouses, Cold Rooms, Trucks

<u>Test</u>	<u>In-house Method</u>	<u>Reference Method</u>
Thermal Profile ¹	PEV.EL.04	USP 39 NF 34 Volume 1, Good Storage and Transportation Practices

Measurements in the Field: Empty and Full Chambers

<u>Test(s)</u>	<u>In-house Method</u>	<u>Reference Method</u>
Characterization of Autoclaves, Comparison of Temperatures - Stability Test and Temperature Uniformity ¹	PEV.EL.01	USP 39 NF 34 Volume 1 Sterilization and Guarantee of Sterility of Pharmaceutical Articles

ELECTRICAL

Measurements in the Field: AC Power Lines

<u>Test(s)</u>	<u>In-house Method</u>	<u>Reference Method</u>
Measurement of Power Frequency Electric and Magnetic Fields from AC Power Lines	PEE.EL.053	IEEE Std 644-1994: IEEE Standard Procedure for Measurement of Power Frequency Electric and Magnetic Fields from AC Power Lines

¹ This laboratory meets A2LA R104 – *General Requirements: Accreditation of Field Testing and Field Calibration Laboratories* for these tests.



Accredited Laboratory

A2LA has accredited

ELICROM CÍA. LTDA.

Guayaquil, ECUADOR

for technical competence in the field of

Mechanical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. 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*).



Presented this 7th day of October 2019.

A blue ink signature of the Vice President of Accreditation Services.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 4286.03
Valid to August 31, 2021

For the tests to which this accreditation applies, please refer to the laboratory's Mechanical Scope of Accreditation.