



# PERRY JOHNSON LABORATORY ACCREDITATION, INC.

## *Certificate of Accreditation*

*Perry Johnson Laboratory Accreditation, Inc. has assessed the Laboratory of:*

***SICAMING México, S.A. de C.V.***

*Dr. Gustavo Baz No. 317, Col. Hipico*

*Metepc, Estado de México, México. C.P. 52156*

*(Hereinafter called the Organization) and hereby declares that Organization 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 (as outlined by the joint ISO-ILAC-IAF Communiqué dated April 2017):

***Thermodynamic and Mechanical Testing***  
*(As detailed in the supplement)*

Accreditation claims for such testing and/or calibration services shall only be made from addresses referenced within this certificate. This Accreditation is granted subject to the system rules governing the Accreditation referred to above, and the Organization hereby covenants with the Accreditation body's duty to observe and comply with the said rules.

For PJLA:

Tracy Szerszen  
President

*Initial Accreditation Date:*

January 15, 2023

*Issue Date:*

January 15, 2023

*Expiration Date:*

October 31, 2024

*Accreditation No.:*

117896

*Certificate No.:*

L23-24

Perry Johnson Laboratory  
Accreditation, Inc. (PJLA)  
755 W. Big Beaver, Suite 1325  
Troy, Michigan 48084

*The validity of this certificate is maintained through ongoing assessments based on a continuous accreditation cycle. The validity of this certificate should be confirmed through the PJLA website: [www.pjllabs.com](http://www.pjllabs.com)*



# Certificate of Accreditation: Supplement

## SICAMING México, S.A. de C.V.

Dr. Gustavo Baz No. 317, Col. Hipico  
Metepc, Estado de México, México. C.P. 52156  
Contact Name: José Angel Felix Phone: 722-270-0239

Accreditation is granted to the facility to perform the following testing:

FIELD OF TEST	ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	RANGE (WHERE APPROPRIATE) AND DETECTION LIMIT
Thermodynamic <sup>o</sup>	Autoclave	Design Qualification Installation Qualification Operating Qualification. Performance Qualification and Stability	Customer Requirements FEUM, USP NOM-059-SSA1 NOM-164-SSA1	100 °C to 140 °C
		Thermal Profile	Customer Requirement of Thermal Profile Studies	
	Oven (Depyrogenation Dry Heat)	Design Qualification Installation Qualification Operating Qualification. Performance Qualification and Stability	Customer Requirements FEUM, USP NOM-059-SSA1 NOM-241-SSA1 NOM-164-SSA1	250 °C (Fixed point) 180 °C (Fixed point)
		Thermal Profile	Customer Requirement of Thermal Profile Studies	
	Drying stove	Design Qualification Installation Qualification Operating Qualification. Performance Qualification and Stability	Customer Requirements FEUM, USP NOM-059-SSA1 NOM-241-SSA1 NOM-164-SSA1	30 °C to 200 °C
		Thermal Profile	Customer Requirement of Thermal Profile Studies	
	Incubators	Design Qualification Installation Qualification Operating Qualification. Performance Qualification and Stability	Customer Requirements FEUM, USP NOM-059-SSA1 NOM-241-SSA1 NOM-164-SSA1	0 °C to 100 °C
		Thermal Profile	Customer Requirement of Thermal Profile Studies	



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Thermodynamic <sup>o</sup>	Refrigerator	Design Qualification Installation Qualification Operating Qualification. Performance Qualification and Stability	Customer Requirements FEUM, USP NOM-059-SSA1 NOM-241-SSA1 NOM-164-SSA1	0 °C to 10 °C
		Thermal Profile	Customer Requirement of Thermal Profile Studies	
	Freezer	Design Qualification Installation Qualification Operating Qualification. Performance Qualification and Stability	Customer Requirements FEUM, USP NOM-059-SSA1 NOM-241-SSA1 NOM-164-SSA1	-30 °C to 0 °C
		Thermal Profile	Customer Requirement of Thermal Profile Studies	
Ultra Low Temperature Freezer		Design Qualification Installation Qualification Operating Qualification. Performance Qualification and Stability	Customer Requirements FEUM, USP NOM-059-SSA1 NOM-241-SSA1 NOM-164-SSA1	-80 °C to -40 °C
		Thermal Profile	Customer Requirement of Thermal Profile Studies	
	Enviromental Chamber and Enviromental Stabilities Chamber and stabilities room (Temperature and % Relativity Humidity)	Design Qualification Installation Qualification Operating Qualification. Performance Qualification and Stability	Customer Requirements FEUM, USP NOM-059-SSA1 NOM-241-SSA1 NOM-164-SSA1 NOM-073-SSA1	0 °C to 100 °C 10 % RH to 90 % RH



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Thermodynamic <sup>o</sup>	Environmental Chamber and Environmental Stabilities Chamber and stabilities room (Temperature and % Relativity Humidity)	Thermal Profile	Customer Requirement of Thermal Profile Studies	0 °C to 100 °C 10 % RH to 90 % RH
	Cold camera	Design Qualification Installation Qualification Operating Qualification. Performance Qualification and Stability	Customer Requirements FEUM, USP NOM-059-SSA1 NOM-241-SSA1 NOM-164-SSA1	0 °C to 10 °C
		Thermal Profile	Customer Requirement of Thermal Profile Studies	
	Muffle	Design Qualification Installation Qualification Operating Qualification. Performance Qualification and Stability	Customer Requirements FEUM, USP NOM-059-SSA1 NOM-241-SSA1 NOM-164-SSA1	0 °C to 1 000 °C
		Thermal Profile	Customer Requirement of Thermal Profile Studies Procedure	
	Lyophilizer		Customer Requirements Thermal Profile Studies Procedure	121 °C (Fixed point) 10 °C to -50 °C -40 °C to 45 °C
	Temperature and Humidity in Storage		Customer Requirements Thermal Profile Studies Procedure	0 °C to 100 °C 10 % RH to 90 % RH



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Thermodynamic <sup>o</sup>	Ethylene Oxide Sterilization Chamber	Thermal Profile	Customer Requirements Thermal Profile Studies Procedure	0 °C to 100 °C
	Fluid Bed Granulator		Customer Requirements Thermal Profile Studies Procedure	0 °C to 100 °C
	Cold Chain and Ambient Temperature		Customer Requirements Thermal Profile Studies Procedure	-30 °C to 30 °C
Mechanical <sup>o</sup>	Biosafety Cabinets Clean rooms (Particle counts, Airflow volume, Temperature, Humidity and Integrity)	Design Qualification Installation Qualification Operating Qualification. Performance Qualification	Customer Requirements FEUM NSF/ANSI 49 NOM-059-SSA1 NOM-241-SSA1 NOM-164-SSA1 ISO14644	0.5 µm to 5 µm 0.36 m/s to 0.54 m/s 18 °C to 25 °C 30 % RH to 75 % RH 0.01 %, 0.05 %, 0.003 %, 0.005 % 100 Lux to 700 Lux
	Laminar Flow Hood (Clean Rooms Particle counts, Airflow volume, Temperature, Humidity and Integrity)		Customer Requirements NOM-059-SSA1 NOM-241-SSA1 NOM-164-SSA1 ISO14644	0.5 µm to 5 µm 0.36 m/s to 0.54 m/s 18 °C to 25 °C 30 % RH to 75 % RH 0.01 %, 0.05 %, 0.003 %, 0.005 % 100 Lux to 700 Lux
	Laminar Flow Modules (Clean Rooms Particle counts, Airflow volume, Temperature, Humidity and Integrity)		Customer Requirements NOM-059-SSA1 NOM-241-SSA1 NOM-164-SSA1 ISO14644	0.5 µm to 5 µm 0.36 to 0.54 m/s 18 °C to 25 °C 30 % RH to 75 % RH 0.01 %, 0.05 %, 0.003 %, 0.005 % 100 Lux to 700 Lux
	Clean Rooms (Particle Counts, Airflow Volume, Temperature, Humidity and Integrity)		Customer Requirements NOM-059-SSA1 NOM-241-SSA1 NOM-164-SSA1 ISO 14644	0.5 µm to 5 µm Up to 2 500 m <sup>3</sup> /h 18 °C to 25 °C 30 % RH to 75 % RH 0.01 µg/L, 0.05 µg/L, 0.003 µg/L, 0.005 µg/L 100 Lux to 700 Lux



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Mechanical <sup>o</sup>	Nitrogen	Design Qualification Installation Qualification Operating Qualification. Performance Qualification	Customer Requirements FEUM NOM-059-SSA1 NOM-241-SSA1 NOM-164-SSA1	0.5 µm to 5 µm Up to 150 ppm CO <sub>2</sub> Up to 3 000 ppm CO <sub>2</sub> Up to 10 ppm CO Up to 1 500 mg/m <sup>3</sup> Water Steam Up to 100 ppm O <sub>2</sub> Up to 10 bar Up to 200 UFC/m <sup>3</sup>
	Compressed Air		Customer Requirements FEUM NOM-059-SSA1 NOM-241-SSA1 NOM-164-SSA1	0.5 µm to 5 µm Up to 150 ppm CO Up to 10 ppm CO Up to 1 500mg/m <sup>3</sup> Water Steam Up to 0.1 mg/m <sup>3</sup> Oil Up to 100 °C Up to 100 % RH -60 Td °C to 20 Td °C Up to 10 bar Up to 200 UFC/m <sup>3</sup>

1. The presence of a superscript O means that the laboratory performs testing of the indicated parameter onsite at customer locations. Example: Outside Micrometer<sup>o</sup> would mean that the laboratory performs this testing onsite at the customer's location.