



INTERNATIONAL
ACCREDITATION
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CERTIFICATE OF ACCREDITATION

This is to attest

MICROBIOLOGIA Y CALIDAD INDUSTRIAL S.A

ZONA FRANCA ZETA MONTECILLOS DE ALAJUELA
BUILDING #33, 20104, COSTA RICA

Testing Laboratory TL-1207

has met the requirements of AC89, *IAS Accreditation Criteria for Testing Laboratories*, and has demonstrated compliance with ISO/IEC Standard 17025:2017, *General requirements for the competence of testing and calibration laboratories*. This organization is accredited to provide the services specified in the scope of accreditation.

Effective Date May 15, 2026



International Accreditation Service
Issued under the authority of IAS management

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SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

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MICROBIOLOGIA Y CALIDAD INDUSTRIAL S.A

Location	Address	Contact Name	Contact Phone	Scope Pages
TL-1207 Main	ZONA FRANCA ZETA, MONTECILLOS DE ALAJUELA BUILDING #33, 20104, COSTA RICA	Yuliana Rojas Ballesterro	+506 4010 3016	2-3
TL-1446 Integrated Location	ZETA INDUSTRIAL PARK, BUILDING 39-N13, GUADALUPE (ARENILLA), 30106, CARTAGO, COSTA RICA	Yuliana Rojas Ballesterro	+506 4010 3016	3

Accredited to ISO/IEC 17025:2017

Effective Date May 15, 2026

TL-1207 Main

FIELDS OF TESTING	MATERIAL/MATRIX	DETERMINANT(S)/ANALYTE(S)	METHOD REFERENCE
Biology	Ambient Air	Viable Particles	TM-001 Analysis of viable particles in ambient air. (Active environmental air sampling) (Based on ISO 14698-1 and BS EN 1714)
	Drinking water, process water	Total coliforms and Escherichia coli	TM-005 Total coliforms and Escherichia coli by quantitative MPN technique using Enzyme Substrate Assay (Colilert®) with Quanti-Tray (Based on Standard Methods for the Examination of Water and Wastewater. 24th ed. APHA Method 9223B)
	Drinking water, process water	Total coliforms and Escherichia coli	TM-005 Total coliforms and Escherichia coli by the qualitative technique of presence or absence using Enzyme substrate assay (Colilert®) with 100 mL bottle (Based on Standard Methods for the Examination of Water and Wastewater. 24th ed. APHA Method 9223B)
	Medical devices, components, raw materials	Bacterial endotoxins	TM-006 Determination of bacterial endotoxins (LAL) by photometric turbidimetric and chromogenic techniques (Based on ANSI/AAMI ST72, USP/NF <85> and LAL)
	Health care products.	Population of the microorganisms	TM-007 Sterilization of health care products. Determination of the population of the microorganisms on product. (Based on ISO 11737-1)



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FIELDS OF TESTING	MATERIAL/ MATRIX	DETERMINANT(S)/ ANALYTE(S)	METHOD REFERENCE
Biology (cont'd.)	Medical and pharmaceutical devices	Sterility testing, bacteriostasis and fungistasis	TM-008 Sterility testing, bacteriostasis and fungistasis in finished goods of both medical devices and pharmaceuticals. (Based on (USP) <71> Sterility test / AAMI / ISO 11737-2)
	Health care products.0	Biological Indicators Testing	TM-009-1 Biological Indicators Testing: Inoculation of Devices and Sterility using culture by immersion in non-selective broth. (Based on USP/NF <1035> and ISO 11138-1)
	Controlled environments, health products	Biochemical identification microbial	TM-011 Biochemical identification microbial by phenotypic (biochemical) method (Based on Vitek 2 Microbial Identification Method and UPS Method <1113>)
	Surfaces	Viable particles	TM-017 Analysis of viable particles on surfaces (Surface viable sampling using contact plates (RODAC)) (Based on ISO 14698-1 and BS EN 17141)
Sampling	Drinking water, process water	Water Sampling	IN-007 Water Sampling (Based on Standard Methods for the Examination of Water and Wastewater 24 th ed. 1060B)
Chemical	Medical Devices	Ethylene Oxide Sterilization Residuals Test	TM-019 Ethylene Oxide Sterilization Residuals Test: Medical Devices (Based on ISO 10993-7. Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals)

TL-1446 Integrated Location

FIELDS OF TESTING	MATERIAL/ MATRIX	DETERMINANT(S)/ ANALYTE(S)	METHOD REFERENCE
Biology	Ambient air	Viable Particles	TM-001 Analysis of viable particles in ambient air. (Active environmental sampling) (Based on ISO 14698-1 and BS EN 1714)
	Surfaces		TM-017 Analysis of viable particles on surfaces (Surface viable sampling using contact plates (RODAC)) (Based on ISO 14698-1 and BS EN 17141)
Sampling	Drinking water, process water	Water Sampling	IN-007 Water Sampling (Based on Standard Methods for the Examination of Water and Wastewater. 24 th ed. 1060B)

