CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

North American Science Associates, Inc. (NAMSA)
9 Morgan
Irvine, CA 92618

Fulfills the requirements of

ISO/IEC 17025:2017

In the field of

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.

R. Douglas Leonard Jr., VP, PILR SBU

Expiry Date: 09 March 2022
Certificate Number: AT-2562

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

North American Science Associates, Inc. (NAMSA)

9 Morgan
Irvine, CA 92618

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TESTING

Valid to: **March 9, 2022** Certificate Number: **AT-2562**

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Infrared Analysis (IR)	ISO 10993-18; USP <197>	Polymers, Non-Volatile Residue, Particulates	FTIR Spectrophotometer
Particulate Analysis	USP <788>; USP <789>; ISO 14708-3	Medical Devices	Particle Counting Apparatus, LAF Hood, Microscope
Ethylene Oxide Residuals Analysis	ISO 10993:7	Medical Devices	Gas Chromatography
USP Total Organic Carbon	USP <643>	Medical Devices	TOC Analyzer

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Cytotoxicity Assay, Elution Method (48-hour Exposure): L929 Cells	ISO 10993-5; USP <87>	Polymers, Metals, Assembled Devices, Materials	Cell Culture Equipment, Microscope
Cytotoxicity Assay, Agarose Overlay: L929 Cells	ISO 10993-5; USP <87>	Polymers, Metals, Assembled Devices, Materials	Cell Culture Equipment, Microscope
USP Limulus Amebocyte Lysate (LAL) Kinetic Turbidimetric Method	USP <85>	Polymers, Metals, Assembled Devices, Materials, Drug Products (Intermediates and Finished)	Spectrophotometer, Incubator

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
USP Limulus Amebocyte Lysate (LAL) Kinetic Chromogenic Method	USP <85>	Polymers, Metals, Assembled Devices, Materials, Drug Products (Intermediates and Finished)	Spectrophotometer, Incubator
USP Limulus Amebocyte Lysate (LAL) Gel Clot Method	USP <85>	Polymers, Metals, Assembled Devices, Materials, Drug Products (Intermediates and Finished)	Incubator, Qualitative Observation

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Bioburden Testing of Medical Products	ISO 11737-1; USP<55>; USP<61>; USP<1231>	Medical Devices, Materials, Pharmaceuticals, Human Tissues	ISO Class 5 Hoods, Incubators
Identification of Microorganisms	Applied Biosystems MicroSEQ® Microbial Identification System Analysis and Interpretation	Medical Devices, Materials, Pharmaceuticals, Human Tissues	ISO Class 5 Hoods, Genetic Sequencer, Thermocyclers
Bacteriostasis/Fungistasis Testing	ISO 11737-2; ISO 11137-2; ISO 11135; USP <71>	Medical Devices, Materials, Pharmaceuticals, Human Tissues	Class 6 Cleanroom, ISO Class 5 Hoods, Incubators
USP Antimicrobial Preservative Effectiveness	USP <51>	Medical Devices, Materials, Pharmaceuticals	ISO Class 5 Hoods, Incubators
Bioburden Recovery Validation	ISO 11737-1; USP<1227>	Medical Devices, Materials, Pharmaceuticals, Human Tissues	ISO Class 5 Hoods, Incubators
Incubation and Enumeration of Fallout Plates, RODAC® Plates, or Air Sampler Media	ISO 14698-1; USP<1116>	Environmental Monitoring	Incubators, Macroscopic Observations
Kirby-Bauer Standard Antimicrobial Susceptibility Test	American Journal of Clinical Pathologists, Volume 95	Medical Devices, Materials, Pharmaceuticals	ISO Class 5 Hoods, Incubators
Determining Antimicrobial Activity of Immobilized Antimicrobial Agents	ASTM E2149	Medical Devices, Materials	ISO Class 5 Hoods, Incubators

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Sterility	ISO 11737-2; ISO 11137-2; ISO 11135; USP <71>	Medical Devices, Materials, Pharmaceuticals, Human Tissues	ISO Class 6 Cleanroom, ISO Class 5 Hoods, Incubators
Gram Stain and Colony Morphology	FDA Microbiological Methods & Bacteriological Analytical Manual (BAM)	Medical Devices, Materials, Pharmaceuticals, Human Tissues	ISO Class 5 Hoods, Incubators, Microscopes

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-2562.

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