CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

NAMSA
8945 Evergreen Boulevard
Minneapolis, MN 55433

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: 21 December 2024
Certificate Number: L2348

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

NAMSA

8945 Evergreen Boulevard
Minneapolis, MN 55433

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TESTING

Valid to: **December 21, 2024** Certificate Number: **L2348**

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Mammalian Erythrocyte Micronucleus Test	ISO 10993-3 BS/EN/ISO 10993-3 (OECD 474)	Finished Medical Devices, and Drugs	Genotoxicity
Guinea Pig Maximization Test	ISO 10993-10 BS/EN/ISO 10993-10 PFSB/ELD/OMDE Notification No. 0301-20, Part 5	Finished Medical Devices, and Drugs	Sensitization
Closed-Patch Test (Buehler)	ISO 10993-10 BS/EN/ISO 10993-10	Finished Medical Devices, and Drugs	Sensitization
Animal Irritation Test	ISO 10993-10 BS/EN/ISO 10993-10	Finished Medical Devices, and Drugs	Irritation
Intracutaneous Reactivity Test	ISO 10993-10 BS/EN/ISO 10993-10 USP 88 PFSB/ELD/OMDE Notification No. 0301-20, Part 5	Finished Medical Devices, and Drugs	Irritation
Vaginal Irritation Test	ISO 10993-10 BS/EN/ISO 10993-10	Finished Medical Devices, and Drugs	Irritation
Primary Buccal (mucosal) Irritation Test	ISO 10993-10 BS/EN/ISO 10993-10	Finished Medical Devices, and Drugs	Irritation
Ocular Irritation Test	ISO 10993-10 BS/EN/ISO 10993-10	Finished Medical Devices, and Drugs	Irritation

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Acute Systemic Toxicity Test	ISO 10993-11 BS/EN/ISO 10993-11 USP 88 PFSB/EDL/OMDE Notification	Finished Medical Devices, and Drugs	Systemic Toxicity
Materials Mediated Pyrogenicity Test; Rabbits	ISO 10993-11 BS/EN/ISO 10993-11 USP 151	Finished Medical Devices, and Drugs	Systemic Toxicity
Systemic Toxicity Test (Implant Method)	ISO10993-11 BS/EN/ISO 10993-11 ISO10993- 6 BS/EN/ISO 10993-6	Finished Medical Devices, and Drugs	Systemic Toxicity
Systemic Toxicity Test (Repeated Exposure Method)	ISO10993- 11 BS/EN/ISO 10993-11	Finished Medical Devices, and Drugs	Systemic Toxicity
Thrombogenicity Test	ISO 10993-4 BS/EN/ISO 10993-4	Finished Medical Devices, and Drugs	Hemocompatibility
Implantation Test	ISO 10993-6 BS/EN/ISO 10993-6	Finished Medical Devices, and Drugs	Local Tissue Effects
Agar Overlay; Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5 USP 87	Finished Medical Devices, and Drugs	Cytotoxicity
Direct Contact Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5 USP 87	Finished Medical Devices, and Drugs	Cytotoxicity
MEM Elution Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5 USP 87	Finished Medical Devices, and Drugs	Cytotoxicity
MTT Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5	Finished Medical Devices, and Drugs	Cytotoxicity
Neutral Red Uptake Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5	Finished Medical Devices, and Drugs	Cytotoxicity
Colony Formation Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5 PFSB/ELD/OMDE Notification No. 0301-20, Part 1	Finished Medical Devices, and Drugs	Cytotoxicity
In-Vitro Skin Sensitization Assay; Human Cell Line Activation Test	OECD 442E	Finished Medical Devices, and Drugs	Sensitization
Direct Peptide Reactivity Assay	OECD 422C	Finished Medical Devices, and Drugs	Sensitization

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
In-Vitro Skin Irritation Assay	OECD 439	Finished Medical Devices and Drugs	Irritation
Hemolysis Assay Extract Method	ISO 10993-4 BS/EN/ISO 10993-4 ASTM F756 PFSB/ELD/OMDE Notification No. 0301-20, Part 8	Finished Medical Devices, and Drugs	Hemocompatibility
Hemolysis Assay; Direct Method	ISO 10993-4 BS/EN/ISO 10993-4 ASTM F756 NIH	Finished Medical Devices, and Drugs	Hemocompatibility
Partial Thromboplastin Time (PTT) Assay	ISO 10993-4 EN/SIO 10993-4 ASTM F2382	Finished Medical Devices, and Drugs	Hemocompatibility
Thrombin Antithrombin Assay	ISO 10993-4 BS/EN/ISO 10993-4	Finished Medical Devices, and Drugs	Hemocompatibility
Complement Activation Assay; SC5b-9 Method	ISO 10993-4 BS/EN/ISO10993-4	Finished Medical Devices, and Drugs	Hemocompatibility
Complement Activation Assay; C3a Method	ISO 10993-4 BS/EN/ISO 10993-4	Finished Medical Devices, and Drugs	Hemocompatibility
Heparinized Blood Platelet and Leukocyte Count Assay	ISO10993- 4 BS/EN/ISO 10993-4 ASTM F2888	Finished Medical Devices, and Drugs	Hemocompatibility
In Vitro Blood Loop Assay (Ovine Blood)	ISO 10993-4 BS/EN/ISO 10993-4	Finished Medical Devices, and Drugs	Hemocompatibility
In Vitro Human Blood Loop Assay	ISO 10993-4 BS/EN/ISO 10993-4	Finished Medical Devices, and Drugs	Hemocompatibility
Bacterial Endotoxin: Kinetic Chromogenic LAL Method	USP 85 USP 161	Finished Medical Devices, and Drugs	Endotoxin
Ames Bacterial Reverse Mutation Assay	ISO 10993-3 BS/EN/ISO 10993-3 (OECD 471) PFSB/ELD/OMDE Notification No. 0301-20, Part 3	Finished Medical Devices, and Drugs	Genotoxicity

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Mouse Lymphoma Assay	ISO 10993-3 BS/EN/ISO 10993-3 (OECD 476) PFSB/ELD/OMDE Notification No. 0301-20, Part 3	Finished Medical Devices, and Drugs	Genotoxicity
Chromosome Aberration Assay	ISO 10993-3 BS/EN/ISO 10993-3 (OECD 473) PFSB/ELD/OMDE Notification No. 0301-20, Part 3	Finished Medical Devices, and Drugs	Genotoxicity

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Chemical Characterization; Extractables / Leachables Analysis	ISO 10993-18 BS/EN/ISO 10993-18	Finished Medical Devices, Drugs, and Packaging	High-Performance Liquid Chromatography (HPLC/UV/MS)
Chemical Characterization; Extractables / Leachables Analysis	ISO 10993-18 BS/EN/ISO 10993-18	Finished Medical Devices, Drugs, and Packaging	Inductively Coupled Plasma Mass Spectrometry (ICPMS)
Chemical Characterization; Extractables / Leachables Analysis	ISO 10993-18 BS/EN/ISO 10993-18	Finished Medical Devices, Drugs, and Packaging	Fourier Transform Infrared Spectroscopy (FTIR)
Chemical Characterization; Extractables / Leachables Analysis	ISO 10993-18 BS/EN/ISO 10993-18	Finished Medical Devices, Drugs, and Packaging	Gas Chromatography Mass Spectrometry (GCMS)

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. L2348.

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