CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

North American Science Associates, LLC (NAMSA)

6750 Wales Road
Northwood, OH 43619

Fulfills the requirements of

ISO/IEC 17025:2017

and

FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Biocompatibility Testing of Medical Devices

and

Good Laboratory Practice for Nonclinical Laboratory Studies, Title 21 CFR Part 58 Accreditation Program

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-2561

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

FDA ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA) PILOT PROGRAM - BIOCOMPATIBILITY TESTING OF MEDICAL DEVICES [1]

GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES, TITLE 21 CFR PART 58 ACCREDITATION PROGRAM [2]

North American Science Associates, LLC (NAMSA)

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Northwood, OH 43619

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TESTING

Valid to: **March 09, 2022** Certificate Number: **AT-2561**

Testing to meet the requirements of ANAB Supplemental Requirements SR 2438, FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Biocompatibility Testing of Medical Devices [1]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials, or Product Tested	Key Equipment or Technology
SC5b-9 Complement Activation (TM_00179)	ISO 10993-4 Third edition 2017-04 Biological evaluation of medical devices- Part 4; ISO 10993-12 Fourth -edition 2012-07-01- Biological evaluation of medical devices – Part 12	Medical Devices	Spectrophotometer (minimum range: 200–1000 nm)

Testing to meet the requirements of ANAB Supplemental Requirements SR 2438, FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Biocompatibility Testing of Medical Devices [1]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials, or Product Tested	Key Equipment or Technology
Direct and Indirect Hemolysis (TM_00177)	ISO 10993-4 Third edition 2017-04 Biological evaluation of medical devices- Part 4; ASTM F756-17; ISO 10993-12 Fourth edition 2012-07-01 Biological evaluation of medical devices – Part 12;	Medical Devices	Incubator (37°C ± 1°C) or (50°/70°C ± 2°C) Autoclave (121°C ± 2°C) Spectrophotometer (minimum range: 200-1000 nm) Centrifuge (minimum range: 600-4000 rpm)
MEM Elution Cytotoxicity (TM_00168)	ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices – Part 5; ISO 10993-12 Fourth edition 2012-07-01 Biological evaluation of medical devices – Part 12	Medical Devices	Shaker-incubator (37°C ± 1°C) Incubator (37°C ± 1°C) and (5% CO_2 ± 1% CO_2)
Skin Irritation (TM_00136)	ISO 10993-10 Third edition 2010-08-01 Biological evaluation of medical devices – Part 10; ISO 10993-12 Fourth edition 2012-07-01 Biological evaluation of medical devices – Part 12	Medical Devices	Shaker-incubator (37°C ± 1°C) or (50°/70°C ± 2°C) Autoclave (121°C ± 2°C)

Testing to meet the requirements of ANAB Supplemental Requirements SR 2438, FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Biocompatibility Testing of Medical Devices [1]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials, or Product Tested	Key Equipment or Technology
Intracutaneous Reactivity Irritation (TM_00129)	ISO 10993-10 Third edition 2010-08-01 Biological evaluation of medical devices – Part 10; ISO 10993-12 Fourth edition 2012-07-01 Biological evaluation of medical devices – Part 12	Medical Devices	Shaker-incubator (37°C ± 1°C) or (50°/70°C ± 2°C) Autoclave (121°C ± 2°C)
Closed Patch Sensitization (TM_00134)	ISO 10993-10 Third edition 2010-08-01 Biological evaluation of medical devices – Part 10;	Medical Devices	Not applicable
Guinea Pig Maximization Sensitization (TM_00135)	ISO 10993-10 Third edition 2010-08-01 Biological evaluation of medical devices – Part 10; ASTM F720-17; ISO 10993-12 Fourth edition 2012-07-01 Biological evaluation of medical devices – Part 12	Medical Devices	Shaker-incubator (37°C ± 1°C) or (50°/70°C ± 2°C) Autoclave (121°C ± 2°C)
Acute Systemic Toxicity (TM_00157)	ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices – Part 11; ISO 10993-12 Fourth edition 2012-07-01 Biological evaluation of medical devices – Part 12	Medical Devices	Shaker-incubator (37°C ± 1°C) or (50°/70°C ± 2°C) Autoclave (121°C ± 2°C) Balance (calibrated daily prior to use)

Testing to meet the requirements of ANAB Supplemental Requirements SR 2438, FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Biocompatibility Testing of Medical Devices [1]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials, or Product Tested	Key Equipment or Technology
Material-Mediated Pyrogenicity (TM_00116)	ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices – Part 11; USP<151>; ISO 10993-12 Fourth edition 2012-07-01 Biological evaluation of medical devices – Part 12	Medical Devices	Shaker-incubator (37°C ± 1°C) or (50°/70°C ± 2°C) Autoclave (121°C ± 2°C) Probes (± 0.1°C)

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Ultra Performance Liquid Chromatography-Mass Spectrometry (UPLC-MS)	ISO 10993-18	Polymers, Metals, Assembled Devices, Materials	Ultra Performance Liquid Chromatograph (UPLC – qTOF)
Gas Chromatography-Mass Spectrometry (GC-MS)	ISO 10993-18	Polymers, Metals, Assembled Devices, Materials	Gas Chromatograph - Mass Spectrometer (GC-MS)
Inductively Coupled Plasma-Mass Spectrometry (ICP-MS)	ISO 10993-18	Polymers, Metals, Assembled Devices, Materials	Inductively Coupled Plasma - Mass Spectrometer (ICP-MS)
Inductively Coupled Plasma-Optical Emission Spectroscopy (ICP-OES)	ISO 10993-18	Polymers, Metals, Assembled Devices, Materials	Inductively Coupled Plasma-Optical Emission Spectrometer (ICP-OES)
Ion Chromatography (IC)	ISO 10993-18	Polymers, Metals, Assembled Devices, Materials	Ion Chromatograph (IC)
Infrared Analysis (IR)	USP <197>; USP <854>	Polymers, Non-Volatile Residue, Particulates	FTIR Spectrophotometer
Exhaustive and Exaggerated Extraction	ISO 10993-18	Polymers, Metals, Assembled Devices, Materials	Balances, Rotary Evaporator, Incubators
Preliminary and Exaggerated Extraction	MHLW	Finished Medical Devices	Balances, Rotary Evaporator, Incubators

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Characterization of Plastic Materials of Construction and Elastomeric Closures (including Physicochemical Testing)	USP38-NF33 <661>; USP <381>; USP <661.1>; USP <661.2>	Polymers, Containers, Closures	FTIR Spectrophotometer, Balances, Rotary Evaporator, Incubators, pH Meter, UV-Vis Spectrophotometer, ICP-MS, Differential Scanning Calorimeter, Chromatography, GC-MS, ICP-MS, UPLC-MS

Biological [2]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Chromosomal Aberration Study in Mammalian Cells	ISO 10993-3; ISO 10993-12; OECD 473; MHLW	Polymers, Metals, Assembled Devices, Materials	Cell Culture Equipment, Microscope
Mouse Lymphoma Assay	ISO 10993-3; ISO 10993-12; OECD 490	Polymers, Metals, Assembled Devices, Materials	Cell Culture Equipment, Cell Counters
Bacterial Reverse Mutation (Ames Test)	ISO 10993-3; ISO 10993-12; OECD 471; MHLW	Polymers, Metals, Assembled Devices, Materials	Bacterial Culture Equipment
In Vivo Thromboresistance Study: Jugular or Carotid	ISO 10993-4	Polymers, Metals, Assembled Devices, Materials	Test System, Scoring
Complement Activation Assay	ISO 10993-4; ISO 10993-12	Polymers, Metals, Assembled Devices, Materials	Spectrophotometer, Elisa
Hemolysis Study	ISO 10993-4; ISO 10993-12; ASTM F756	Polymers, Metals, Assembled Devices, Materials	Spectrophotometer
Partial Thromboplastin Time	ISO 10993-4; ISO 10993-12; ASTM F2382	Polymers, Metals, Assembled Devices, Materials	Coagulation Analyzer
Cytotoxicity Assay, Elution Method	ISO 10993-5; ISO 10993-12; USP <87>	Polymers, Metals, Assembled Devices, Materials	Cell Culture Equipment, Microscope
Cytotoxicity Assay, Agarose Overlay	ISO 10993-5; ISO 10993-12; USP <87>	Polymers, Metals, Assembled Devices, Materials	Cell Culture Equipment, Microscope
Cytotoxicity Assay, Direct Contact	ISO 10993-5; ISO 10993-12	Polymers, Metals, Assembled Devices, Materials	Cell Culture Equipment, Microscope

Biological [2]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Cytotoxicity, Colony Assay	MHLW Part 1 ISO 10993-5; ISO 10993-12	Polymers, Metals, Assembled Devices, Materials	Cell Culture Equipment, Microscope
Cytotoxicity Assay, MTT	ISO 10993-5; ISO 10993-12	Polymers, Metals, Assembled Devices, Materials	Cell Culture Equipment, Microscope, Spectrophotometer
Cytotoxicity Study using a modified ISO and USP Method	NAMSA TM_00205; TM_00210: Modified ISO 10993-5; ISO 10993-12; USP <87>	Polymers, Metals, Assembled Devices, Materials	Cell Culture Equipment, Microscope
Subcutaneous Implantation Study	ISO 10993-6	Polymers, Metals, Assembled Devices, Materials	Test System, Clinical Observations, Scoring, Tissue Evaluation, Histopathology
Muscle Implantation Study	ISO 10993-6; USP <88>; MHLW Part 4	Polymers, Metals, Assembled Devices, Materials	Test System, Clinical Observations, Scoring, Tissue Evaluation, Histopathology
Bone Implantation Study	ISO 10993-6	Polymers, Metals, Assembled Devices, Materials	Test System, Clinical Observations, Scoring, Tissue Evaluation, Histopathology
Intracutaneous Reactivity Study	ISO 10993-10; ISO 10993-12; USP <88>; MHLW Part 5	Polymers, Metals, Assembled Devices, Materials	Test System, Clinical Observations, Scoring
Skin Irritation Study	ISO 10993-10; ISO 10993-12	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Scoring
Oral Mucosal Irritation Study	ISO 10993-10; ISO 10993-12	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Scoring, Tissue Evaluation, Histopathology
Vaginal Irritation Study	ISO 10993-10; ISO 10993-12	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Scoring, Tissue Evaluation, Histopathology
Urinary Bladder Irritation Study	ISO 10993-10; ISO 10993-12	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Scoring, Tissue Evaluation, Histopathology
Penile Irritation Study	ISO 10993-10; ISO 10993-12	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Scoring, Tissue Evaluation, Histopathology

Biological [2]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Sensitization Study, Maximization Method	ISO 10993-10; ISO 10993-12; USP <88>; MHLW Part 6	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Scoring
Sensitization Study, Closed Patch Method	ISO 10993-10	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Scoring
Systemic Toxicity Study	ISO 10993-11; ISO 10993-12; USP <88>; MHLW Part 6	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Scoring
Pyrogen or Material Mediated Pyrogen Study	ISO 10993-11; ISO 10993-12; USP <151>; MHLW Part 7; EP 6.0 Section 2.6.8; JP 4.04	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Thermometer Readings
Subchronic/Chronic Toxicity Study, Subcutaneous	ISO 10993-11; ISO 10993-6; ISO 10993-12	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Scoring, Tissue Evaluation, Histopathology
Subchronic Toxicity Study	ISO 10993-11; ISO 10993-12	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Tissue Evaluation, Histopathology

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Gram Stain and Colony Morphology	FDA Microbiological Methods & Bacteriological Analytical Manual (BAM)	Medical Devices, Biologics, Materials	ISO Class 5 Hoods, Biosafety Cabinets, Macroscopic Observations, Microscope
Bioburden Testing of Medical Products	ISO 11737-1; USP <55>; USP <61>; USP <1231>	Medical Devices, Materials	ISO Class 5 Hoods, Incubators
Bacteriostasis/Fungistasis Testing	ISO 11737-2; ISO 11137-2; USP <71>	Medical Devices, Materials	ISO Class 6 Cleanroom, 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
Bioburden Recovery Validation	ISO 11737-1; USP <1227>	Medical Devices, Materials	ISO Class 5 Hoods, Incubators
Incubation and Enumeration on Fallout Plates, RODAC® Plates, or Air Sampler Media	ISO 14698-1; USP <1116>	Environmental Monitoring	Incubators, Macroscopic Observations
Total Viable Spore Count	USP <55>	Biologics, Process Challenge Devices (PCDs)	ISO Class 5 Hoods, Incubators
Sterility Testing	ISO 11737-2; ISO 11137-2; USP <71>	Medical Devices, Biologics, Materials	ISO Class 6 Cleanroom, ISO Class 5 Hoods, Incubators

Note:

1. Testing is in conformance to the FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Biocompatibility Testing of Medical Devices.
2. Biological testing is in conformance to the U.S. FDA GLP (Good Laboratory Practice) Regulations per 21 CFR Part 58.
3. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-2561.

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