CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Nelson Laboratories, LLC

6280 S. Redwood Road
Salt Lake City, UT 84123

Fulfills the requirements of

ISO/IEC 17025:2017

and

ANAB Supplemental Requirements SR 2438, 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.

Jason Stine, Vice President

Expiry Date: 16 March 2027

Certificate Number: AT-1382.03

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

AND

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

Nelson Laboratories, LLC

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Salt Lake City, UT 84123

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TESTING

ISO/IEC 17025 Accreditation Granted: **16 March 2025**

Certificate Number: **AT-1382.03** Certificate Expiry Date: **16 March 2027**

Testing to meet the requirements of ANAB Supplemental Requirements SR 2438, 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
MEM Elution Cytotoxicity	ANSI AAMI ISO 10993-5:2009/(R)2014 Biological evaluation of medical devices – Part 5 (FDA Recognition No.2-245); ANSI AAMI ISO 10993-12:2012 Biological evaluation of medical devices -part 12 (FDA Recognition No. 2-191)	Medical Devices	ISO Class 5 Hoods, Microscope, Incubators

Note:

1. Testing to meet the requirements of ANAB Supplemental Requirements SR 2438, FDA Accreditation Scheme for Conformity Assessment (ASCA) Program – Biocompatibility Laboratories meeting these requirements are eligible to apply to participate in the FDA ASCA program. Participation in the FDA ASCA program can be confirmed by visiting their website https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/asca-accredited-testing-laboratories. .

Jason Stine, Vice President

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