



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

ELEMENT CINCINNATI
3701 Port Union Road
Fairfield, Ohio 45014
Meghan Smith Phone: 513 984 4112

BIOLOGICAL

Valid To: April 30, 2026

Certificate Number: 2422.02

In recognition of the successful completion of the A2LA evaluation process accreditation is granted to this laboratory to perform the following types of tests on medical devices and water:

<u>Test Description:</u>	<u>Method(s):</u>
Particulate Matter in Injection Scope Expansion In future -I reviewed operation of equipment. Perhaps by the end of April. DLA 4/26/24	USP788
Limulus Amebocyte Lysate (LAL)	USP 85; ANSI/AAMI ST72
Bioburden	ISO 11737-1
Total Aerobic Microbial Count, Total Yeast and Mold Count-Microbial Limits	USP 61
Total Microbial Count in Water	USP 1231 Section 8
<i>Escherichia coli, Salmonella, Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans, Clostridia species</i>	USP 62
Cytotoxicity	ISO 10993-5; USP 87
Heterotrophic Plate Count	SM 9215
Bacteriostasis/Fungistasis Testing	AAMI/ANSI/ISO 11737-2; /USP <71>
Sterility Test Procedure	AAMI/ANSI/ISO 11737-2; /USP <71>

CHEMICAL

<u>Test Description:</u>	<u>Method(s):</u>
TOC	SM 5310C; USP 643
Conductivity	USP 645
Gravimetric	ASTM F2459-18 11.5 and 11.8



Accredited Laboratory

A2LA has accredited

ELEMENT CINCINNATI

Fairfield, OH

for technical competence in the field of

Biological Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. 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).



Presented this 12th day of June 2024.

A blue ink signature of Mr. Trace McInturff, written over a horizontal line.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 2422.02
Valid to April 30, 2026

For the tests to which this accreditation applies, please refer to the laboratory's Biological Scope of Accreditation.