



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

STERIS LABORATORIES, INC.
9303 West Broadway Ave
Brooklyn Park MN, 55445
Beth Jacques Phone: 763-315-1200

BIOLOGICAL

Valid To: January 31, 2027

Certificate Number: 4350.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following test on medical devices, environmental samples, and cosmetics.

<u>Test</u>	<u>Method(s)</u>	<u>Laboratory Procedure</u>
Bacterial Testing:		
Antimicrobial Effectiveness Test	USP <51>	Q08-WI-001744
Biological Monitoring-Culturing and Enumeration	ISO 14698-1	Q08-WI-001746
Microbial Limits Tests	USP <61>, <62>	Q08-WI-001730
Organism Identification by MALDI-TOF	N/A	Q08-WI-001739 Q08-WI-001772
Pseudomonas Liquid Testing	N/A	Q08-WI-001749
Total Coliforms and <i>Escherichia coli</i> Testing	Standard Methods for the Examination of Water and Wastewater	Q08-WI-001741
Mycology Testing:		
Antimicrobial Effectiveness Test	USP <51>	Q08-WI-001744
Biological Monitoring-Culturing and Enumeration	ISO 14698-1	Q08-WI-001746
Microbial Limits Tests	USP <61>, <62>	Q08-WI-001730
Organism Identification by MALDI-TOF	N/A	Q08-WI-001739 Q08-WI-001772

<u>Test</u>	<u>Method(s)</u>	<u>Laboratory Procedure</u>
Sterility Testing:		
Bacteriostasis/ Fungistasis Testing	AAMI/ANSI/ISO 11737-2/ USP <71>	Q08-WI-001728
Sterility Test Procedure	AAMI/ANSI/ISO 11737-2/ USP <71>	Q08-WI-001720
Bioburden Testing:		
Bioburden Product Test	AAMI/ANSI/ISO 11737-1	Q08-WI-001719
Bioburden Test Method Validation	AAMI/ANSI/ISO 11737-1	Q08-WI-001743
Liquid Bioburden Procedure	N/A	Q08-WI-001742
Bacterial Endotoxin Testing:		
Limulus Amebocyte Lysate Test	AAMI ST72/ USP <85>, <161> 11737-3	Q08-WI-001722
Cytotoxicity Testing:		
Cytotoxicity – 3T3 Neutral Red Uptake Assay	ISO 10993-5 Neutral Red Uptake (NRU)	Q08-WI-001759

CHEMICAL

<u>Test</u>	<u>Method(s)</u>	<u>Laboratory Procedure</u>
Ethylene Oxide Residue (Oxide, Chlorohydrin)	ISO 10993-7	Q08-WI-001745
Total Organic Carbon Testing	USP <643>	Q08-WI-001756





Accredited Laboratory

A2LA has accredited

STERIS LABORATORIES, INC.

Brooklyn Park, MN

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 18th day of November 2024.

A blue ink signature of Mr. Trace McInturff, written in a cursive style.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 4350.01
Valid to January 31, 2027

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