

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

STERIS LABORATORIES, INC.  
9303 West Broadway Ave  
Brooklyn Park MN, 55445  
Jean Gerlach Phone: 763-315-1205

BIOLOGICAL

Valid To: January 31, 2023

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 and clean rooms:

<u>Test</u>	<u>Test Method(s)</u>	<u>Laboratory Procedure</u>
<b>Bacterial Testing:</b>		
Antimicrobial Effectiveness Test	USP <51>	LAB-061
Enumeration and Identification	ISO 14698-1	LAB-066
Microbial Limits Tests	USP <61>, <62>	LAB-019
Pseudomonas Liquid Testing	N/A	LAB-080
Total Coliforms and <i>Escherichia coli</i> Testing	Standard Methods for the Examination of Water and Wastewater	LAB-055
<b>Mycology Testing:</b>		
Antimicrobial Effectiveness Test	USP <51>	LAB-061
Enumeration and Identification	ISO 14698-1	LAB-066
Microbial Limits Tests	USP <61>, <62>	LAB-019

<u>Test</u>	<u>Test Method(s)</u>	<u>Laboratory Procedure</u>
<b>Sterility Testing:</b>		
Bacteriostasis/ Fungistasis Testing	AAMI/ANSI/ISO 11737-2/ USP <71>	LAB-015
Sterility Test Procedure	AAMI/ANSI/ISO 11737-2/ USP <71>	LAB-003
<b>Bioburden Testing:</b>		
Bioburden Product Test	AAMI/ANSI/ISO 11737-1	LAB-002
Bioburden Test Method Validation	AAMI/ANSI/ISO 11737-1	LAB-060
Liquid Bioburden Procedure	N/A	LAB-059
<b>Bacterial Endotoxin Testing:</b>		
Limulus Amebocyte Lysate Test	AAMI ST72/ USP <85>, <161>	LAB-005
<b>Cytotoxicity Testing:</b>		
Cytotoxicity – 3T3 Neutral Red Uptake Assay	ISO 10993-5 Neutral Red Uptake (NRU)	LAB-099



# 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 19<sup>th</sup> day of November 2020.

A blue ink signature of a person, written in a cursive style.

Vice President, Accreditation Services  
For the Accreditation Council  
Certificate Number 4350.01  
Valid to January 31, 2023

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