



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

Steris Laboratories, Inc.
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BIOLOGICAL

Valid To: October, 31, 2024

Certificate Number 7181.01

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(s)</u>	<u>Method(s)</u>	<u>Laboratory Procedure</u>
Water Testing:		
Heterotrophic Plate Count (HPC)	Standard Methods for the Examination of Water and Wastewater	Q08-WI-002540
Total Coliform (TC)/ Fecal Coliform (FC)	Standard Methods for the Examination of Water and Wastewater	Q08-WI-002540
Bacteriology:		
Enumeration	ISO 14698-1	Q08-WI-002579
Identification	ISO 14698-1	Q08-WI-002538
Sterility:		
Bacteriostasis/Fungistasis Testing	ANSI/AAMI/ISO 11737-2/ USP <71>	Q08-WI-002545
Sterility Test	ANSI/AAMI/ISO 11737-2/ USP <71>	Q08-WI-002550 Q08-WI-002551
Endotoxin:		
Gel Cot Method	AAMI ST72/ USP <85>, <161>	Q08-WI-002543
Kinetics Method	AAMI ST72/ USP <85>, <161>	Q08-WI-002575
Biocompatibility:		
Cytotoxicity in-vitro	ISO 10993-5 Neutral Red Uptake (NRU)	Q08-WI-002573
Bioburden:		
Bioburden Test	ANSI/AAMI/ISO 11737-1	Q08-WI-002544
Bioburden Test Method Validation	ANSI/AAMI/ISO 11737-1	Q08-WI-002555 Q08-WI-002571

CHEMICAL

<u>Test(s)</u>	<u>Method(s)</u>	<u>Laboratory Procedure</u>
Residual Testing:		
Ethylene Oxide Residue (Oxide, Chlorohydrin)	ISO 10993-7	Q08-WI-002532





Accredited Laboratory

A2LA has accredited

STERIS LABORATORIES INC.

El Paso, TX

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 10th day of October 2023.

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 7181.01
Valid to October 31, 2024
Revised November 2, 2023

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