



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

STERIS LABORATORIES, INC
1880 Industrial Drive
Libertyville, IL 60048
Leslie Pusz Phone: (708)205-2841
Carrie Osing Phone: (847)367-5259
Latrice Sutherland Phone: (847)247-4782

BIOLOGICAL

Valid To: January 31, 2025

Certificate Number: 5914.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on Medical Devices (including implantable), Tissue (support SAL validation), and Sterile Medical Devices:

<u>Test/Technology</u>	<u>Reference Method(s)</u>	<u>Local Procedure(s)</u>
Bacterial Endotoxin (LAL) Test	ANSI/AAMI ST72, USP <85>, USP <161>	WI-01743
Bioburden Test	ANSI/AAMI/ISO 11737-1	WI-01749
Method Suitability Bacteriostasis / Fungistasis Test	ANSI/AAMI/ISO 11737-2, USP <71>	WI-01812
Recovery Efficiency Test	ANSI/AAMI/ISO 11737-1	WI-01752
Sterility Test	ANSI/AAMI/ISO 11737-2, USP <71>	WI-01722



Accredited Laboratory

A2LA has accredited

STERIS LABORATORIES, INC. Libertyville, IL

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 3rd day of November 2022.

A blue ink signature of Mr. Trace McInturff.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 5914.01
Valid to January 31, 2025

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