



CERTIFICATE OF ACCREDITATION

ANSI-ASQ National Accreditation Board

500 Montgomery Street, Suite 625, Alexandria, VA 22314, 877-344-3044

This is to certify that

Dynatec Scientific Laboratories, Inc.
11940 Golden Gate Road
El Paso, TX 79936

has been assessed by ANAB
and meets the requirements of international standard

ISO/IEC 17025:2005

while demonstrating technical competence in the field(s) of

TESTING

Refer to the accompanying Scope(s) of Accreditation for information regarding the types of tests to which this accreditation applies.

AT-1372

Certificate Number

ANAB Approval

Certificate Valid: 02/13/2017-01/31/2019
Version No. 003 Issued: 02/13/2017



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005. 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 January 2009).



ANSI-ASQ National Accreditation Board

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

Dynatec Scientific Laboratories, Inc

11940 Golden Gate Road El Paso, TX 79936

Rudy Pina Phone: 915-849-1322 ext. 102

TESTING

Valid to: January 31, 2019

Certificate Number: AT - 1372

I. Chemical

ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	*KEY EQUIPMENT OR TECHNOLOGY
Finished Medical Devices/Components Biological Products	Biocompatibility Test for Residual Analysis Ethylene Oxide, Ethylene Chlorohydrin, & Ethylene Glycol	ISO 10993-7 Biological evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals	Gas Chromatography
	Packaging Testing and Validation Seal Strength Accelerated Aging Microbiological Barrier Testing	ASTM F 88 Standard Test Method for Seal Strength of Flexible Barrier Materials. ASTM F 1585 Standard Guide for Integrity Testing of Porous Barrier Medical Packages ASTM F 1980 Standard Guide for Accelerated Aging of Sterile Medical Device Packages ISO 11607 Packaging for Terminally Sterilized Medical Devices	Environmental Chamber Tensile Tester
	Reusable Validation of Reusable Devices	AAMI ST35 Biological Decontamination of Reusable Devices AAMI TIR12 Designing, Testing, and Labeling Reusable Medical Devices AMMI TIR 30 A Compendium of Processes, Materials Test Methods and Acceptance Criteria for Cleaning Reusable Medical Devices	Artificial Test Soil



II. Biological

ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	*KEY EQUIPMENT OR TECHNOLOGY
<p>Finished Medical Devices/Components</p> <p>Biological Products</p>	<p>Sterilization</p> <p>Microbiological Sterilization Validation of Products</p> <p>Sterilized by:</p> <ul style="list-style-type: none"> • Ethylene Oxide • Radiation • Steam • Gamma 	<p>ISO 11737-2 Sterilization of Medical Devices Microbiological Methods – Part 2: Test of sterility performed in the validation of a sterilization process</p> <p>ISO 11135 Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization</p> <p>ISO 11137 Sterilization of Healthcare Products- Requirements for Validation and Routine Control-Radiation Sterilization</p> <p>ISO 17665-1 Sterilization of Health Care Products – Moist Heat Part 1 Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices</p> <p>Tech. Report No. 3 PDA Validation of Dry Heat Process Use for Sterilization and Depyrogenation</p> <p>AAMI TIR33 Substantiation of Selected Sterilization Dose- Method VD-max</p> <p>ISO 11138 Sterilization of Health Care Products-Biological Indicators-Part 1: General Requirements</p>	<p>Steam Sterilizer</p> <ul style="list-style-type: none"> • Pre-Vac, 3013 • Gravity, 3011 <p>Biological Indicators</p> <p>Incubators</p>
	<p>Water Testing</p> <p>Heterotrophic Plate Count (HPC) Total Coliform (TC) Fecal Coliform (FC)</p>	<p>Standard Methods for the Examination of Water, Waste Water 21st Edition Method 9215, 9222B & D / Hach Method 8074 & 10029/ FDA / BAM Bacteriological Analytical Manual</p>	<p>Membrane Filtration</p>
	<p>Bacteriology</p> <p>Identification of Microorganisms Molds Pathogens</p>	<p>Bergey’s Manual of Determinative Bacteriology – Ninth Edition Microbiological Identification System (MIS)</p>	<p>Agilent Gas Chromatography Microscopy</p>
	<p>Endotoxin</p> <p>Gel Clot Method Kinetics Method</p>	<p>AAMI ST72 Bacterial Endotoxin-Test Method-ologies, Routine Monitoring, and Alternatives to Batch Testing</p> <p>FDA Guidelines Validation Limulus Amebocyte Lysate Gel Clot and Kinetics</p> <p>USP Endotoxin Test Monograph <85></p>	<p>Kinetic Method: KC4-Bio-tek Micro Plate Reader ELX 808</p>

ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	*KEY EQUIPMENT OR TECHNOLOGY
<p>Finished Medical Devices / Components</p> <p>Biological Products</p>	<p>Biocompatibility</p> <p>Cytotoxicity in-vitro</p>	<p>ISO 10993-5; 10993-12 Extract, Direct-Contact and Indirect-Contact</p>	<p>Cell Lysis</p>
	<p>Bioburden Levels</p> <p>Contact Lenses Finished Medical Devices/Components Biological Products Cosmetics Raw Material</p> <ul style="list-style-type: none"> Aerobic, Anaerobic, Spore Former, Mold, Spore Count 	<p>FDA Guidelines Aerobic Bioburden Membrane Filtration Shake Method ANSI/AAMI/ISO 11737-1 Sterilization of Medical Devices – Microbiological Methods – Part 1: Determination of Population of Microorganisms on Products</p>	<p>Incubators Filtration Systems Shakers</p>
	<p>Clean Room/Hood Certification</p> <p>Classification Non-Viable Particulates Viable Particulates Air</p> <p>Viable Particulates Surface/Water</p> <p>Compressed Air</p> <p>Personnel</p> <ul style="list-style-type: none"> Apparel Hygiene 	<p>ISO 14698-2; 14698-3 Cleanroom and Associated Controlled Environments – Bio-Contamination Control – Parts 2 and 3</p> <p>ISO 14644-1; 14644-2 Cleanroom and Associated Controlled Environments – Parts 1 and 2</p> <p>IES-RP-CC006-2; IES-RP-C0012-1; IES-RP-CC09.2; IES-RP-CC011.2 Institute of Environmental Sciences</p> <ul style="list-style-type: none"> Consideration in Clean Room Design Documents Relating to Contamination Control <p>IENT-RP-CC00.2 Contamination Control Division RP 002.2 Unidirectional Flow Clean-Air Devices EN 724 Clean Room - Microbiological Control JIS-B-9923 Surface Particle Counters JIS-B-19924 Clean Room Garments - Methods for Sizing/Counting Particle Contaminants and On Clean Room Garments ISO 8573 Part 1,2,3,4,5,7 Compressed Air</p>	<p>Particle Counter (Particles/ ft³)</p> <p>Air Samplers</p> <p>Cultured Media</p> <p>Slit to Agar Sampler</p> <p>Aerosol Generator</p>



ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	*KEY EQUIPMENT OR TECHNOLOGY
Medical Devices	<p style="text-align: center;">Sterilization Cycle Development</p> <p>Temperature / Humidity Distribution</p> <p>EO Penetration</p> <p>Material / Package Compatibility</p> <p>Process Challenge Device (PCD) Development</p> <p>Comparative Resistance</p> <p>Microbial Lethality</p>	<p style="text-align: center;">ISO 11135 Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization</p> <p style="text-align: center;">AAMI TIR 14 Contract Sterilization using Ethylene Oxide</p> <p style="text-align: center;">AAMI TIR 16 Process development and performance qualification for ethylene oxide sterilization – Microbiological aspects</p> <p style="text-align: center;">ANSI/AAMI/ISO 14161 Biological indicators – Guidance for the selection, use and interpretation of results</p> <p style="text-align: center;">ANSI/AAMI/ISO 11138 Biological indicators – Part 1 and Part 2</p> <p style="text-align: center;">AAMI TIR 31 Process challenge devices / test packs for use in health care facilities</p> <p style="text-align: center;">AAMI TIR 20 Parametric release for EO sterilization</p>	EO Sterilizer

Notes:

1. * = As Applicable
2. This scope is part of and must be included with the Certificate of Accreditation No. AT- 1372.


 Vice President