CERTIFICATE OF ACCREDITATION

ANSI National Accreditation Board

11617 Coldwater Road, Fort Wayne, IN 46845 USA

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 of

TESTING

Refer to the accompanying Scope of Accreditation for information regarding the types of activities to which this accreditation applies

AT-1372
Certificate Number

ANAB Approval

Certificate Valid Through: 01/31/2021
Version No. 005 Issued: 01/31/2019

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 April 2017).

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

Dynatec Scientific Laboratories, Inc.

11940 Golden Gate Road
El Paso, TX 79936

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TESTING

Valid to: **January 31, 2021** Certificate Number: **AT-1372**

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
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	Finished Medical Devices/Components Biological Products	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	Finished Medical Devices/Components Biological Products	Environmental Chamber Tensile Tester

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
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	Finished Medical Devices/Components Biological Products	Artificial Test Soil

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Sterilization Microbiological Sterilization Validation of Products Sterilized by: • Ethylene Oxide • Radiation • Steam • Gamma	**ISO 11737-2** Sterilization of Medical Devices Microbiological Methods – Part 2: Test of sterility performed in the validation of a sterilization process **ISO 11135** Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization **ISO 11137** Sterilization of Healthcare Products-Requirements for Validation and Routine Control-Radiation Sterilization **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 **Tech. Report No. 3 PDA** Validation of Dry Heat Process Use for Sterilization and Depyrogenation **AAMI TIR33** Substantiation of Selected Sterilization Dose-Method VD-max **ISO 11138** Sterilization of Health Care Products-Biological Indicators-Part 1: General Requirements	Finished Medical Devices/Components Biological Products	Steam Sterilizer • Pre-Vac, 3013 • Gravity, 3011 Biological Indicators Incubators

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Water Testing Heterotrophic Plate Count (HPC) Total Coliform (TC) Fecal Coliform (FC)	Standard Methods for the Examination of Water, Waste Water 21st Edition Method 9215, 9222B & D / Hach Method 8074 & 10029/ FDA / BAM Bacteriological Analytical Manual	Finished Medical Devices/Components Biological Products Water	Membrane Filtration
Bacteriology Identification of Microorganisms Fatty Acid Methyl Esters (FAME) Analysis Molds Pathogens	Bergey's Manual of Determinative Bacteriology – Ninth Edition Microbiological Identification System (MIS)	Finished Medical Devices/Components Biological Products	Agilent Gas Chromatography Microscopy
Endotoxin Gel Clot Method Kinetics Method	**AAMI ST72** Bacterial Endotoxin-Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing **FDA Guidelines** Validation Limulus Amebocyte Lysate Gel Clot and Kinetics USP Endotoxin Test Monograph <85>	Finished Medical Devices/Components Biological Products	Kinetic Method: KC4-Bio-tek Micro Plate Reader ELX 808
Biocompatibility Cytotoxicity in-vitro	**ISO 10993-5; 10993-12** Extract, Direct-Contact and Indirect-Contact	Finished Medical Devices/Components Biological Products	Cell Lysis

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Bioburden Levels Contact Lenses Finished Medical Devices/Components Biological Products Cosmetics Raw Material • Aerobic, Anaerobic, Spore Former, Mold, Spore Count	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	Finished Medical Devices/Components Biological Products	Incubators Filtration Systems Shakers

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Clean Room/Hood Certification Classification Non-Viable Particulates Viable Particulates Air Viable Particulates Surface/Water Compressed Air Personnel • Apparel • Hygiene	**ISO 14698-2;14698-3** Cleanroom and Associated Controlled Environments – Bio-Contamination Control – Parts 2 and 3 **ISO 14644-1; 14644-2** Cleanroom and Associated Controlled Environments – Parts 1 and 2 **IES-RP-CC006-2; IES-RP-C0012-1; IES-RP-CC09.2; IES-RP-CC011.2** Institute of Environmental Sciences • Consideration in Clean Room Design • Documents Relating to Contamination Control **IEST-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	Finished Medical Devices/Components Biological Products	Particle Counter (Particles/ ft^3) Air Samplers Cultured Media Slit to Agar Sampler Aerosol Generator

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Sterilization Cycle Development, Routine Processing and R&D Temperature / Humidity Distribution EO Penetration Material / Package Compatibility Process Challenge Device (PCD) Development Comparative Resistance Microbial Lethality	**ISO 11135** Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization **AAMI TIR 14** Contract Sterilization using Ethylene Oxide **AAMI TIR 16** Process development and performance qualification for ethylene oxide sterilization – Microbiological aspects **ANSI/AAMI/ISO 14161** Biological indicators – Guidance for the selection, use and interpretation of results **ANSI/AAMI/ISO 11138** Biological indicators – Part 1 and Part 2 **AAMI TIR 31** Process challenge devices / test packs for use in health care facilities **AAMI TIR 20** Parametric release for EO sterilization	Medical Devices	EO Sterilizer

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-1372.

Vice President