

Certificate of Accreditation



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

having satisfactorily demonstrated conformance to the requirements of

ISO/IEC 17025:2005

and technical competence for the activities identified on the attached schedule,

TUV Rheinland of North America, Inc.

hereby grants accreditation for the following activities:

Testing

Initial Approval: January 26, 2004

Current Approval: January 26, 2007

Current Expiration: January 25, 2010

Accreditation Certificate 74 400 2521

Revision: 1

A handwritten signature in black ink, appearing to read 'Dave Moody'.

Dave Moody – Program Manager

Laboratory Accreditation Services

Schedule of Accreditation



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Parameter	Test Reference	Title
Biocompatibility	ANSI/AAMI St72; 2002	Bacterial Endotoxins – Test Methodologies, Routine Monitoring, And Alternatives To Batch Testing
	ANSI/AAMI St 29; 1988	Determining Residual Ethylene Oxide In Medical Devices
	ANSI/AAMI St30; 1989	Determining Ethylene Chlorohydrins And Glycol In Medical Devices
	ANSI/AAMI TIR No. 19; 1998	Guidance For Biological Evaluation Of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals
	ISO/EN 10993-7	Biological Evaluation Of Medical Devices – 7 Ethylene Oxide Sterilization Residual
	ASTM Designation: F 813; 1983 (Reapproved 1995)	Standard Practice For Direct Contact Cell Culture Evaluation Of Materials For Medical Devices
	ASTM Designation: F895; 1984	Stand Method For Agar Diffusion Cell Culture Screening For Cytotoxicity

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Parameter	Test Reference	Title
Biocompatibility	ISO/EN 10993-5	Biological Evaluation Of Medical Devices – Part 5 Tests For Cytotoxicity: In Vitro Methods
	AAMI/Volume 4S2; 2000	Biological Evaluation Of Medical Devices, Supplement 2 10993-5, 10993-9, 10993-13 TRI No. 19/A1
	AAMI/Volume 4; 1997	Biological Evaluation Of Medical Devices 10993-1, 10993-2, 10993-3, 10993-4, 10993-5, 10993-6, 10993-7.14155, 10993-9, 10993-10, 10993-11, 10993-12
	AAMI/Volume 4S; 1998	Biological Evaluation Of Medical Devices, Supplemental 10993-1, 10993-16
	ANSI/AAMI/ISO 10993-8; 2000	Biological Evaluation Of Medical Devices – Part 8: Selection And Qualification Of Reference Material For Biological Tests
	Food And Drug Administration Guideline; May 1997	Guidance Document For Daily Wear Contact Lenses

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Parameter	Test Reference	Title
Cleanrooms	ISO/DIS 14698-2; 14698-3	Cleanroom And Associated Controlled Environments – Bio-Contamination Control – Part 2 And Part 3
	ISO 14644-1; 14644-2	Cleanroom And Associated Controlled Environments – Part 1 And Part 2
	IES-RP-CC006.2;	Institute Of Environmental Sciences <ul style="list-style-type: none">▪ Consideration In Cleanroom Design▪ Documents Relating To Contamination Control▪ Terms And Definitions
	IES-RP-C0012-1	
	IES-RP-CC09.2;	
	IES-RP-CC011.2	
	IEST-RP-CC002.2; 1999	Contamination Control Division Recommended Practice 002.2 Unidirectional Flow Clean-Air Devices
	EN 724; 1994	Cleanroom-Micro-Biological Control
	JIS-B-9923	Surface Particle Counters
	JIS-B-19924	Cleanroom Garment-Methods For Sizing And Counting Particle Contaminants And On Clean Room Garments

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Parameter	Test Reference	Title
Environmental	Standard Methods (20 th Edition)	Standard Methods For The Examination Of Water/Waste Water: <ul style="list-style-type: none">▪ HPC▪ Total Coliform▪ Fecal Coliform
Microbiology And Mycology Identifications	EMPAT Certification Dynatec Scientific Laboratories Standard Operating Procedure L. 43 Bacteriology	American Institute For Industrial Hygienists Dynatec Scientific Laboratories Standard Operating Procedure For Identifications

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Product Validation Physical Testing	ASTM F88-00	Standard Test Method For Seal Strength Of Flexible Barrier Materials.
	ASTM F1509	Standard Test Method For Determining Acceptability Of Ribbon Welds On Fabric Cartridges.
	AAMI TIR 17	Accelerated Aging – Radiation Sterilization – Material Qualification
	JIS-L-1902; 1990	JIS Testing Method For Antibacterial Of Textiles
	F-1585-00; 06/2000	Standard Guide For Integrity Testing Of Porous Barrier Medical Packages
	AASI/AAMI ST35; 1991	Biological Decontamination Of Reusable Devices
	AAMI/TRI No. 12; 1994	Designing, Testing, And Labeling Reusable Medical Devices

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Sterility Assurance	ISO/EN 11135	Medical Devices – Validation And Routine Control Of Ethylene Oxide Sterilization
	ISO/EN 11137	Sterilization Of Healthcare Products – Requirements For Validation And Routine Control – Radiation Sterilization
	ISO 11134	Sterilization – Industrial Moist Heat
	Tech. Report No. 3 PDA; 1981	Validation Of Dry Heat Processes Use For Sterilization And Depyrogenation
	AAMI/ISO 14160; 1998	Sterilization Of Single-Use Medical Devices- Validation And Routine Control Of Sterilization
	AAMI/Volume 1.1; 1998	Sterilization, Part 1 Sterilization In Healthcare Facilities ST46, ST37, ST42, ST40, ST33, TIR3, ST41, ST43, TIR7, ST35, ST58, TIR12
	AAMI/Volume 1.2; 1998	Sterilization Part 2 Sterilization Equipment ST44, ST45, ST21, ST19, ST8, ST24, ST50, ST55

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Sterility Assurance	AAMI/Volume 1.3; 1999	Sterilization, Part 3 Industrial Process Control 11134, TIR13, 11135, TIR14, TIR15, 10993-7, TIR19, ST34, 11137, TIR13409, TIR17, ST60, 14160, 11737-1, 11737-2, 11607, TIR22
	AAMI TIR No. 13409; 1996/2000	Substantiation 25 kGys (Amendment 1)
	AAMI/ISO TIR No. 15844; 1998	Sterilization Of Health Care Products-Radiation Sterilization-Section Of A Sterilization Dose For A Single Production Batch
	pEN 551;1994	Sterilization Of Medical Devices – Method For Validation And Routine Control Of Ethylene Oxide Sterilization - Guidance
	prEN 533;1991	Sterilization Of Medical Devices – Method For Validation And Routine Control By Irradiation - Guidance
	BS EN 552;1994	Sterilization Of Medical Devices – Method For Validation And Routine Control Of Sterilization By Irradiation

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Parameter	Test Reference	Title
Sterility Assurance	BS EN 550;1994	Sterilization Of Medical Devices – Validation And Routine Control Of Ethylene Oxide Sterilization
	AAMI/TIR27;2001	Sterilization Of Health Care Products – Radiation Sterilization – Substantiation Of 25 kGy As A Sterilization Dose Method VD Max
	ANSI/AAMI.ISO TIR 15843;2000	Sterilization Of Health Care Products – Radiation Sterilization – Product Families And Sampling Plans For Verification Dose Experiments And Sterilization Dose Audits, And Frequency Of Sterilization Dose Audits
	AAMI/DS-2 ST11138-1 (AAMI/CDV-2 ST11138-1); 1995-12-5	Sterilization Of Health Care Products- Biological Indicators-Part 1: General Requirements
	ISO 11607;2003-0215	Packaging For Terminally Sterilized Medical Devices

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