

# TECHSTREET® ENTERPRISE

## STANDARDS AND GUIDELINES FOR MEDICAL DEVICE MANUFACTURING

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#### AAMI

Human Factors Engineering  
Liquid Barrier Performance of Protective Apparel and Drapes  
Requirements for Products Labeled 'STERILE'  
Bacterial Endotoxins  
Steam Sterilization and Sterility Assurance  
Comprehensive Guide to Steam Sterilization and Sterility Assurance  
Medical Devices for Reprocessing in Health Care Facilities  
Sterilization Using Ethylene Oxide  
Microbiological Aspects of Ethylene Oxide Sterilization  
Compatibility of Materials Subject to Sterilization  
Guidance for ANSI/AAMI/ISO 11607 – Packaging for Sterilized Medical Devices  
Product Process Equivalency for Ethylene Oxide Sterilization  
Acceptance Criteria for Cleaning Reusable Medical Devices  
Sterilization – Radiation – Method VDmax  
Application of Usability Engineering to Medical Devices  
Sterilization of Health Care Products – Radiation – Part 2  
Symbols to be Used with Medical Device Labels  
Guidance for ANSI/AAMI/ISO 10993-7 – Part 7: Ethylene Oxide Sterilization Residuals

#### ASME

Engineering Drawing Practices  
Line Conventions and Lettering  
Revision of Engineering Drawings & Associated Documents  
Digital Product Definition Data Practices  
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Dimensioning and Tolerancing

#### ASQ

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#### ASTM

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Conditioning Containers, Packages, or Packaging Components for Testing  
Drop Test of Loaded Containers by Free Fall

Peel or Stripping Strength of Adhesive Bonds  
Vibration Testing of Shipping Containers  
Specification of Pharmaceutical Manufacturing Systems and Equipment  
Intramedullary Fixation Devices  
Titanium Alloy for Surgical Implant Applications  
Microbial Ranking of Porous Packaging Materials  
Determining Integrity of Seals for Flexible Packaging  
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Accelerated Aging of Sterile Barrier Systems  
Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)  
Design and Evaluation of Primary Flexible Packaging  
Seal Strength of Flexible Barrier Materials

#### BSI

Information Supplied by Manufacturers of Medical Devices  
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Ethylene Oxide Sterilizers  
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Large Steam Sterilizers  
Radio-Frequency Disturbance Characteristics  
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#### ISO

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Good Clinical Practice  
Symbols to be Used with Medical Device Labels – Part 1  
Symbols to be Used with Medical Device Labels  
Cardiovascular Implants Part 2: Vascular Stents  
Conical Fittings for Syringes, Needles and Other Medical Equipment – Part 1  
Conical Fittings for Syringes, Needles and Other Medical Equipment – Part 2  
Competence of Testing and Calibration Laboratories

**PRODUCT SETS****ISO**

01.040.03: Sociology  
 01.040.11: Health Care Technology  
 01.040.25: Manufacturing Engineering  
 01.040.31: Electronics  
 01.070: Color Coding  
 01.080.10: Public Information Symbols  
 01.080.20: Graphical Symbols  
 01.080.99: Other Graphical Symbols  
 01.120: Standardization  
 03.120.10: Quality Management  
 03.120.20: Product and Company Certification  
 03.120.30: Application of Statistical Methods  
 07.100.10: Medical Microbiology  
 11.040.01: Medical Equipment  
 11.040.10: Anaesthetic, Respiratory and Reanimation equipment  
 11.040.20: Transfusion, Infusion and Injection Equipment  
 11.040.25: Syringes, Needles and Catheters  
 11.040.30: Surgical Instruments and Materials  
 11.040.40: Implants for Surgery, Prosthetics and Orthotics  
 11.040.70: Ophthalmic Equipment  
 11.040: Medical Equipment  
 11.060.20: Dental Equipment  
 11.080.01: Sterilization and Disinfection  
 11.080.30: Sterilized Packaging  
 11.100.20: Biological Evaluation of Medical Devices  
 11.100: Laboratory Medicine  
 13.020.10: Environmental Management

13.040.30: Workplace Atmospheres  
 13.040.35: Cleanrooms and Controlled Environments  
 13.060.60: Physical Properties of Water  
 13.180: Ergonomics  
 13.220.40: Ignitability and Burning Behavior of Materials  
 13.340.10: Protective Clothing  
 17.020: Metrology and Measurement  
 17.040.01: Linear and Angular Measurements  
 17.040.20: Properties of Surfaces  
 17.040.30: Measuring Instruments  
 17.160: Shock and Vibration Measurements  
 21.060.10: Bolts, Screws, Studs  
 21.060.20: Nuts  
 25.220.20: Surface Treatment  
 25.220: Surface Treatment and Coating  
 31.260: Optoelectronics, Laser Equipment  
 35.040: Character Sets and Information Coding  
 35.080: Software Development and System Documentation  
 35.180: IT Terminals and Other Peripherals  
 35.240.15: Identification Cards  
 47.020.10: Hulls and Structural Elements  
 55.180.40: Filled Transport Packages  
 71.040.30: Chemical Reagents  
 71.100.60: Essential Oils  
 81.040.30: Glass Products  
 83.060: Rubber  
 83.080.01: Plastics  
 83.080.20: Thermoplastic Materials

**AAMI**

AAMI Electromedical Equipment  
 AAMI General and Miscellaneous  
 AAMI Product Set

**ASHRAE**

ASHRAE Product Set

**ASME**

ASME 2010 BPVC Product Set

**ASTM**

ASTM Current Product Set  
 ASTM Section 12 – Health Care Product Set  
 ASTM Volume 13.01 – Medical Devices; Emergency Medical Services

**CGA**

CGA Product Set

**CLSI**

CLSI Product Set

**ICC**

ICC Current Product Set

**ISEA**

ISEA Product Set  
 ISPE Product Set

**NFPA**

NFPA (Fire) Codes and Handbooks

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