

Techstreet Enterprise

Standards and guidelines for medical device manufacturing

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Document list

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

Cleaning, Descaling, and Passivation of Stainless Steel Parts
 Chemical Passivation Treatments for Stainless Steel Parts
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 Rubber Properties – Durometer Hardness
 Performance Testing of Shipping Containers
 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
 Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
 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
 Requirements for Labeling Medical Devices Containing Phthalates
 Large Steam Sterilizers
 Radio-Frequency Disturbance Characteristics
 Sterilization of Medical Devices

Requirements for Medical Devices to be Designated Sterile
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 Sterilization – Ethylene Oxide
 Sterilization of Radiation Products
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 Clinical Investigation of Medical Devices for Human Subjects
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 Proving Compliance with ISO 14644-1
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 Design and Construction of Cleanrooms
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IEC

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 Medical Electrical Equipment – Part 1-11
 Medical Electrical Equipment – Part 1-2
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 Electromagnetic Compatibility (EMC) – Part 4-5
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 Application of Usability Engineering to Medical Devices
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ISO

Biological Evaluation – Part 12
 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
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 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
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 17.040.01: Linear and Angular Measurements
 17.040.20: Properties of Surfaces
 17.040.30: Measuring Instruments
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 21.060.10: Bolts, Screws, Studs
 21.060.20: Nuts
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35.240.15: Identification Cards
47.020.10: Hulls and Structural Elements
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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

Medical device industry Building Blocks

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