Techstreet Enterprise

Standards and guidelines for medical device manufacturing

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Document list

AAMI

- ☐ AAMI HE75: Human Factors Engineering
- ☐ AAMI PB70: Liquid Barrier Performance of Protective Apparel and Drapes
- ☐ AAMI ST67: Requirements for Products Labeled 'STERILE'
- ☐ AAMI ST72: Bacterial Endotoxins
- ☐ AAMI ST79 & A1, A2: Steam Sterilization and Sterility Assurance
- ☐ AAMI ST79 & A1, A2, A3: Comprehensive Guide to Steam Sterilization and Sterility Assurance
- ☐ AAMI TIR12: Medical Devices for Reprocessing in Health Care Facilities
- ☐ AAMI TIR14: Sterilization Using Ethylene Oxide
- ☐ AAMI TIR16: Microbiological Aspects of Ethylene Oxide Sterilization
- ☐ AAMI TIR17: Compatibility of Materials Subject to Sterilization
- ☐ AAMI TIR22 & TIR22/A1: Guidance for ANSI/AAMI/ISO 11607 - Packaging for Sterilized Medical Devices
- ☐ AAMI TIR28: Product Process Equivalency for Ethylene Oxide Sterilization
- ☐ AAMI TIR30: Acceptance Criteria for Cleaning Reusable Medical Devices
- ☐ AAMI TIR33: Sterilization - Radiation - Method VDmax
- ☐ AAMI/IEC 62366: Application of Usability Rngineering to Medical Devices
- ☐ AAMI/ISO 11137-2: Sterilization of Health Care Products - Radiation - Part 2
- ☐ AAMI/ISO 15223-1: Symbols to be Used with Medical Device Labels
- ☐ AAMI/ISO TIR19: Guidance for ANSI/AAMI/ISO 10993-7 - Part 7: Ethylene Oxide Sterilization Residuals

ASME

- ☐ ASME B31.3: Process Piping
- ☐ ASME Y14.100: Engineering Drawing Practices
- ☐ ASME Y14.2M: Line Conventions and Lettering
- ☐ ASME Y14.35M: Revision of Engineering Drawings & Associated Documents
- ☐ ASME Y14.41: Digital Product Definition Data Practices
- ☐ ASME Y14.5.1M: Mathematical Definition of Dimensioning and Tolerancing
- ☐ ASME Y14.5: Dimensioning and Tolerancing

ASQ

- ☐ ASQ S1: An Attribute Skip-Lot Sampling Program
- ☐ ASQ Z1.4: Sampling Procedures and Tables for Inspection by Attributes
- ☐ ASQ Z1.9: Inspection by Variables for Percent Nonconforming

ASTM

- ☐ ASTM A380: Cleaning, Descaling, and Passivation of Stainless Steel Parts

- ☐ ASTM A967: Chemical Passivation Treatments for Stainless Steel Parts
- ☐ ASTM B348: Titanium and Titanium Alloy Bars and Billets
- ☐ ASTM D2240: Rubber Properties - Durometer Hardness
- ☐ ASTM D4169: Performance Testing of Shipping Containers
- ☐ ASTM D4332: Conditioning Containers, Packages, or Packaging Components for Testing
- ☐ ASTM D5276: Drop Test of Loaded Containers by Free Fall
- ☐ ASTM D903: Peel or Stripping Strength of Adhesive Bonds
- ☐ ASTM D999: Vibration Testing of Shipping Containers
- ☐ ASTM E2500: Specification of Pharmaceutical Manufacturing Systems and Equipment
- ☐ ASTM F1264: Intramedullary Fixation Devices
- ☐ ASTM F136: Titanium Alloy for Surgical Implant Applications
- ☐ ASTM F1608: Microbial Ranking of Porous Packaging Materials
- ☐ ASTM F1886/F1886M: Determining Integrity of Seals for Flexible Packaging
- ☐ ASTM F1929: Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ☐ ASTM F1980: Accelerated Aging of Sterile Barrier Systems
- ☐ ASTM F2096: Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ☐ ASTM F2097: Design and Evaluation of Primary Flexible Packaging
- ☐ ASTM F88/F88M: Seal Strength of Flexible Barrier Materials

BSI

- ☐ BS EN 1041: Information Supplied by Manufacturers of Medical Devices
- ☐ BS EN 13060 +A2: Small Steam Sterilizers
- ☐ BS EN 1422 +A1: Ethylene Oxide Sterilizers
- ☐ BS EN 15986: Requirements for Labelling Medical Devices Containing Phthalates
- ☐ BS EN 285 +A2: Large Steam Sterilizers
- ☐ BS EN 55011+A1: Radio-Frequency Disturbance Characteristics
- ☐ BS EN 556-1: Sterilization of Medical Devices
- ☐ BS EN 556-2: Requirements for Medical Devices to be Designated STERILE
- ☐ BS EN 62366: Application of Usability Engineering to Medical Devices
- ☐ BS EN 868-5: Packaging for Terminally Sterilized Medical Devices
- ☐ BS EN 980: Symbols for Labelling Medical Devices
- ☐ BS EN ISO 10993-1: Biological Evaluation Within a Risk Management Process
- ☐ BS EN ISO 10993-10: Biological Evaluation - Irritation and Skin Sensitization
- ☐ BS EN ISO 10993-12: Biological Evaluation of Medical Devices
- ☐ BS EN ISO 10993-13: Biological Evaluation- Degradation from Polymeric Medical Devices
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- ☐ BS EN ISO 10993-5: Biological Evaluation - In vitro Cytotoxicity
- ☐ BS EN ISO 11135-1: Sterilization - Ethylene Oxide
- ☐ BS EN ISO 11137-2: Sterilization of Radiation Products
- ☐ BS EN ISO 11138-2: Sterilization - Biological Indicators for Ethylene Oxide Sterilization
- ☐ BS EN ISO 11607-1: Packaging for Terminally Sterilized Medical Devices
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- ☐ BS EN ISO 11737-1: Sterilization - Microbiological Methods
- ☐ BS EN ISO 13485: Quality Management Systems - Requirements for Regulatory Purposes
- ☐ BS EN ISO 14155: Clinical Investigation of Medical Devices for Human Subjects
- ☐ BS EN ISO 14644-1: Classification of Air Cleanliness
- ☐ BS EN ISO 14644-2: Proving Compliance with ISO 14644-1
- ☐ BS EN ISO 14644-3: Cleanrooms and Associated Controlled Environments
- ☐ BS EN ISO 14644-4: Design and Construction of Cleanrooms
- ☐ BS EN ISO 14644-5: Operation of Cleanrooms

- ☐ BS EN ISO 14644-6: Cleanrooms - Vocabulary
- ☐ BS EN ISO 14644-8: Cleanrooms - Airborne Molecular Contamination
- ☐ BS EN ISO 14698-1: Cleanrooms - Biocontamination Control - General Principles and Methods
- ☐ BS EN ISO 14698-2: Cleanrooms - Biocontamination Control - Evaluation and Interpretation of Data
- ☐ BS EN ISO 14937: Sterilization - Characterization of a Sterilizing Agent
- ☐ BS EN ISO 14971: Application of Risk Management to Medical Devices
- ☐ BS EN ISO 15223-1: Symbols to be Used with Medical Device Labels
- ☐ BS EN ISO 17665-1: Sterilization - Moist Heat
- ☐ BS EN ISO 9001: Quality Management Systems - Requirements

IEC

- ☐ IEC 60529 Ed. 2.1 b: Degrees of Protection Provided by Enclosures
- ☐ IEC 60601-1 Ed. 3.1 en: Medical Electrical Equipment - Part 1
- ☐ IEC 60601-1-1 Ed. 2.0 b: Medical Electrical Equipment - Part 1-1
- ☐ IEC 60601-1-11 Ed. 1.0 b: Medical Electrical Equipment - Part 1-11
- ☐ IEC 60601-1-2 Ed. 3.0 b: Medical Electrical Equipment - Part 1-2
- ☐ IEC 60601-1-4 Ed. 1.1 b: Medical Electrical Equipment - Part 1-4
- ☐ IEC 60601-1-6 Ed. 3.0 b: Medical Electrical Equipment - Part 1-6
- ☐ IEC 60601-1-8 Ed. 2.0 b: Medical Electrical Equipment - Part 1-8
- ☐ IEC 60601-1-SER Ed. 1.0 b: Medical Electrical Equipment - ALL PARTS
- ☐ IEC 60601-2-22 Ed. 3.0 b: Medical Electrical Equipment - Part 2-22
- ☐ IEC 61000-4-2 Ed. 2.0 b: Electromagnetic Compatibility (EMC) - Part 4-2
- ☐ IEC 61000-4-3 Ed. 3.2 b: Electromagnetic Compatibility (EMC) - Part 4-3
- ☐ IEC 61000-4-5 Ed. 2.0 b: Electromagnetic Compatibility (EMC) - Part 4-5
- ☐ IEC 62304 Ed. 1.0 b: Medical Device Software Life Cycle Processes
- ☐ IEC 62366 Ed. 1.0 b: Application of Usability Engineering to Medical Devices
- ☐ IEC/TR 60878 Ed. 2.0 b: Graphical Symbols for Electrical Equipment

ISO

- ☐ ISO 10993-12: Biological Evaluation - Part 12
- ☐ ISO 14155: Good Clinical Practice
- ☐ ISO 15223-1: Symbols to be Used with Medical Device Labels - Part 1
- ☐ ISO 15223-2: Symbols to be Used with Medical Device Labels
- ☐ ISO 25539-2: Cardiovascular Implants - Part 2: Vascular Stents
- ☐ ISO 594-1: Conical Fittings for Syringes, Needles and Other Medical Equipment - Part 1
- ☐ ISO 594-2: Conical Fittings for Syringes, Needles and Other Medical Equipment - Part 2
- ☐ ISO/IEC 17025: Competence of Testing and Calibration Laboratories

Product sets

AAMI

- ☐ AAMI Electromedical Equipment
- ☐ AAMI General and Miscellaneous
- ☐ AAMI Product Set

ASHRAE

- ☐ ASHRAE Product Set

ASME

- ☐ ASME 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

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: Laboratory Medicine
- ☐ 11.100.20: Biological Evaluation of Medical Devices
- ☐ 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
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- ☐ 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

NFPA

- ☐ NFPA (Fire) Codes and Handbooks

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