

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 Engineering 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

BS EN ISO 10993-16: Biological Evaluation – Degradation and Leachables

BS EN ISO 10993-18: Biological Evaluation – Chemical Characterization of Materials

BS EN ISO 10993-4: Biological Evaluation – Interactions with Blood

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

BS EN ISO 11607-2: Packaging – Validation Requirements for Forming, Sealing and Assembly

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  
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

## **NFPA**

NFPA (Fire) Codes and Handbooks

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