Guidelines and Standards

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Standard / Guideline	Name
Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities	AAMI ST79
Sterilization of health care productsRadiation sterilization—Product adoption and alternative sampling plans for verification dose experiments and sterilization dose audits	AAMI TIR35:2016/(R)2021
Sterilization of health care products - Radiation - Guidance on sterilization of human tissue-based products	AAMI TIR37: 2013
Sterilization of health care products-Radiation	AAMI TIR40:2018
Guidelines on the Calibration of Temperature and/or Humidity Controlled Enclosures	AFNOR NF X 15-140
Dry heat (heated air) sterilizers	ANSI/AAMI ST50:2004/(R)2018
Table-top steam sterilizers	ANSI/AAMI ST55:2016/(R)2023
Comprehensive guide to steam sterilization and sterility assurance in health care facilities	ANSI/AAMI ST79
Hospital steam sterilizers	ANSI/AAMI ST8:2013/(R)2018
Sterilization of health care products - Radiation	ANSI/AAMI/ISO 11137-03: 2017
Sterilization of health care products—Biological indicators—Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes	ANSI/AAMI/ISO 11138-5:2017/ (R)2024
Sterilization of health care products—Radiation—Substantiation of selected sterilization dose: Method VDmaxSD	ANSI/AAMI/ISO 13004:2022
Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices	ANSI/AAMI/ISO 14937:2009/(R)2013
Sterilization of health care products -Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices	ANSI/AAMI/ISO 11135:2014
Sterilization of health care products - Moist Heat	ANSI/AAMI/ISO TIR17665-2:2009/ (R)2016
Sterilization of health care products - Chemical indicators	CAN/CSA-ISO 11140-3
Sterilization of health care products - Vocabulary of terms used in sterilization and related equipment and process standards	CSA ISO 11139
Sterilization of health care products - Microbiological methods	CSA ISO 11737-1
Sterilization of health care products - Dry heat - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 20857:2010, IDT)	CSA ISO 20857
Sterilization of health care products - Moist heat	CSA Z17665-1
Electrical laboratory devices - Heating ovens and incubators	DIN 12880

Requirements for the validation of cleaning and disinfection processes	DIN 58341
Sterilization of health care products - Radiation - Confirmation of selected sterilization dose: Method	DIN CEN ISO/TS 13004
Biotechnology - Performance criteria for steam sterilizers and autoclaves	DIN EN 12347
Temperature recorders for the transport, storage and distribution of temperature	DIN EN 12830
Sterilization - Steam sterilizers - Large sterilizers	DIN EN 13060
Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing	DIN EN 14180
Controlled environment storage cabinet for processed thermolabile endoscopes	DIN EN 16442
Sterilizers for medical purposes - Low temperature vapourized hydrogen peroxide sterilizers - Requirements and testing	DIN EN 17180
Sterilization - Steam sterilizers - Large sterilizers	DIN EN 285
Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization	DIN EN 550
Sterilization of medical devices - Validation and routine control of sterilization by moist heat	DIN EN 554 (replaced by DIN ISO 17665)
Sterilization of medical devices	DIN EN 556
Environmental testing	DIN EN 60068
Non-biological systems for use in sterilizers - Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers	DIN EN 867-5
General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices	DIN EN ISO 14937
Sterilization of health-care products - Ethylene oxide; Requirements for the development, validation and routine control of a sterilization process for medical devices	DIN EN ISO 11135
Sterilization of health care products - Biological indicators	DIN EN ISO 11138
Sterilization of health care products - Chemical indicators	DIN EN ISO 11140
Sterilization of health care products - Chemical indicators - Guidance for selection, use and interpretation of results	DIN EN ISO 15882
Washer-disinfector; Performance requirements and test method criteria for demonstrating cleaning efficacy.	DIN EN ISO 15883
Sterilization of health care products - Biological and chemical indicators - Test equipment	DIN EN ISO 18472
Specifies requirements for the development, validation and routine control of a dry heat sterilization process for medical devices	DIN EN ISO 20857
Sterilizers for medical purposes - Small steam sterilizers	DIN EN ISO 13060
Calibration of Climatic Chambers	DKD-R 5-7
Manufacture of Sterile Medicinal Products	EU GMP Annex 01

Manufacture of Biological Medicinal Products for Human Use	EU GMP Annex 02
Manufacture of Radiopharmaceuticals	EU GMP Annex 03
Computerised Systems	EU GMP Annex 11
Qualification and Validation	EU GMP Annex 15
Pharmaceutical Quality System	EU GMP Chapter 1
Premises and Equipment	EU GMP Chapter 3
Production	EU GMP Chapter 5
Quality Control	EU GMP Chapter 6
Current Good Manufacturing Practice in Manufacturing Processing, packing, or Holding of Drugs	FDA 21 CFR part 210
Current Good Manufacturing Practice for Finished Pharmaceuticals	FDA 21 CFR part 211
Regulations on electronic records and electronic signatures	FDA 21 CFR part11
FDA Guide to Inspections of Lyophilization of Parenteral	FDA Inspection Guide
FDA Guide to Inspections of Sterile Drug Substance Manufacturers	FDA Inspection Guide
FDA Guide to Inspections of Pharmaceutical Quality Control Labs	FDA Inspection Guide
FDA Guide to Inspections of Foreign Medical Device Manufacturers	FDA Inspection Guide
FDA Guide to Inspections of Foreign Pharmaceutical Manufacturers	FDA Inspection Guide
FDA Inspection Technical Guide Water for Pharmaceutical Use	FDA Inspection Guide
FDA Instection Technical Guide Expiration Dating and Stability Testing for Human Drug Products	FDA Inspection Guide
Validation and periodic testing of the various sterilization processes used in hospitals, laboratories and other healthcare facilities	HTM 2010
Stability testing of active pharmaceutical ingredients and finished pharmaceutical products	ICH Guideline - Annex10
Targeted Revisions of the ICH Stability Guideline Series	ICH Guideline - Q1/Q5C EWG
Pharmaceutical Quality System	ICH Guideline - Q10
Stability testing of Biotechnological / Biological products	ICH Guideline - Q1A
Stability testing of New Drug Substances and Products	ICH Guideline - Q5C
Quality Risk Management	ICH Guideline - Q9
Stability Testing of new drug substances and products	ICH Q1A (R2)
Environmental testing	IEC 60068
Thermocouples	IEC 60584-1
Industrial Platinum Resistance Thermometers	IEC 60751
ILAC Guidelines for Measurement Uncertainty in Testing	ILAC G17

Measurement management systems — Requirements for measurement processes and measuring equipmen	ISO 10012
Sterilization of health care products; requirements for validation and routine control; industrial moist heat sterilization	ISO 11134
Sterilization of health care products - Radiation	ISO 11137
Sterilization of health care products - General requirements for characterization of a sterilizing agent and for the development, validation and routine control of a sterilization process	ISO 14937
Sterilization of health care products - Moist heat	ISO 17665
Testing and calibration laboratories	ISO/IEC 17025
Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	ISO/WD 22441
Controlled Temperature Chamber Mapping and Monitoring	ISPE Good Practice Guide
Validation of Moist Heat Sterilization Processes Cycle Design, Development, Qualification and Ongoing Control	PDA Technical Report No. 01
Validation of Dry Heat Processes Used for Depyrogenation and Sterilization	PDA Technical Report No. 03
Design Concepts For the Validation of a Water for Injection System	PDA Technical Report No. 04
Parametric Release of Pharmaceuticals and Medical Device Products Terminally Sterilized by Moist Heat	PDA Technical Report No. 30
Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products	PDA Technical Report No. 34
Moist Heat Sterilizer Systems: Design, Commissioning, Operation, Qualification	PDA Technical Report No. 48
Implementation of Quality Risk Management For Pharmaceutical and Biotechnology Manufacturing Operations	PDA Technical Report No. 54
Process Validation: A Lifecycle Approach Annex 1: Oral Solid Dosage/Semisolid/ Dosage Forms	PDA Technical Report No. 60
Data Integrity Management System for Pharmaceutical Laboratorie	PDA Technical Report No. 80
Guide to Good Manufacturing Practice for Medicinal Products	PIC/S (PE 009-17)
Chapters on Good Storage and Distribution Practices	USP (1079) Series
Monitoring Devices—Time, Temperature, and Humidity	USP (1118)
WHO Guidelines on quality and risk management	WHO Guidelines