European Norms (EN) and/or International Standards (ISO) for sterilizers, packaging material, sterilization monitoring and validation

1. **ISO/TS 11139 Terms and definitions in sterilization standards**

2. **EN ISO 11138 Biological indicators to test sterilization processes**
   - Part I General requirements
   - Part II for ethylene oxide sterilization (strips and self-contained)
   - Part III for moist heat sterilization (strips and self-contained)
   - Part IV for dry heat sterilization
   - Part V for low-temperature-steam-formaldehyde sterilization

   EN ISO 14161 Guidance for the selection, use and interpretation of results for the validation and routine monitoring of the sterilization of medical products with biological indicators

3. **EN ISO 11140 Non-biological (chemical) indicators to test sterilization processes**
   - Part I Classification and general requirements (of classes 1-6)
   - Part II not applicable (DIN EN ISO 18472)
   - Part III Requirements Bowie-Dick test sheets
   - Part IV Test procedure for the Bowie-Dick-Simulation Test for steam penetration according to the European standard EN 285 (7 kg)
   - Part V Test procedure for the Bowie-Dick-Simulation Test for air removal

   (only ISO) according to the AAMI test pack (4 kg)

   EN ISO 15882 Guidance for selection, use and interpretation of results for chemical indicators (currently updated to conform with the new EN-ISO 11140 Standard)

   EN ISO 18472 Requirements for test sterilizers (resistometer) to test biological and chemical indicators

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European Norms (EN) and/or International Standards (ISO) for sterilizers, packaging material, sterilization monitoring and validation

4. Standards for validation of medical devices

EN ISO 17665 (replaces EN 554) — **Requirements for the development, validation and routine control of steam sterilization processes**

- Part I Requirements
- Part II Guidance

EN ISO 11135 (replaces EN 550) — **Requirements for the development, validation and routine control of ethylene oxide sterilization processes**

- Part I Requirements
- Part II Guidance

EN ISO 11137 (replaces EN 552) — **Radiation sterilization**

- Part I Requirements for validation and routine control
- Part II Selection of dose setting for products
- Part III Guidance

EN ISO 14937 — **General requirements for the characterization of sterilization products and the development, validation and routine monitoring of sterilization processes**

EN 15424 — **Validation of Low Temperature-Steam-Formaldehyde (LTSF) Processes**

EN ISO 17664 — **Information to be provided by the manufacturer for the processing of re-sterilizable medical devices**

ISO 14971 — **Application of risk management to medical devices**

European Norms (EN) and/or International Standards (ISO) for sterilizers, packaging material, sterilization monitoring and validation

5. EN 868 Packaging materials for sterilization

Part I General requirements for the validation of packaging
Part II Requirements and tests for sterilization wraps
Part III Requirements and tests for paper to manufacture bags
Part IV Requirements and tests for paper bags
Part V Requirements and tests for heat sealable pouches and reel material made of paper and/or plastic and/or laminates
Part VI Requirements and tests for paper to manufacture bags for ethylene oxide and irradiation sterilization
Part VII Requirements and tests for adhesive coated paper to manufacture bags for ethylene oxide and irradiation sterilization
Part VIII Requirements and tests for reusable containers
Part IX Uncoated non-woven materials of polyolefines for use in the manufacturing of heat sealable pouches, reels and lids - Requirements and test methods
Part X Adhesive coated non-woven materials of polyolefines for use in the manufacturing of heat sealable pouches, reels and lids – Requirements and test methods

EN-ISO 11607 Packaging for terminally sterilized medical devices

Part I Requirements for materials, sterile barrier systems and packaging
Part II Validation requirements for forming, sealing and assembly processes

It has been decided to merge EN 868 Part I and ISO 11607 Part I and II in the future.

European Norms (EN) and/or International Standards (ISO) for sterilizers, packaging material, sterilization monitoring and validation

6. EN ISO 15883 Requirements for washers-disinfectors

Part I	General requirements, definitions and tests
Part II	Surgical instruments, anesthetic equipment, hollow ware, utensils, glassware etc.
Part III	Human waste containers (bed pan WD)
Part IV	Thermo-labile re-usable instruments including endoscopes
Part V	Ultrasound – hand cleaning

European Norms (EN) and/or International Standards (ISO) for sterilizers, packaging material, sterilization monitoring and validation

7. Technical requirements for sterilizers

EN 285 Healthcare steam sterilizers > 54 l
EN 13060 Small steam sterilizers < 54 l

EN 13060 divides small steam sterilizers into the following classes:

Steam sterilization process	Application	Class
Fractionated vacuum	all types of packaged, hollow, solid and porous goods have to be tested with the test device Hollow A	**B**
Gravity displacement or single vacuum	non-packaged, solid goods to be used immediately after sterilization or for goods to be sterilized to prevent cross-infections (no hollow devices)	**N**
Depending on the manufacturer‘s specification	goods, specified by the manufacturer	**S**

Sterilizers of class B require fractionated vacuum.
All other sterilizers with gravity cycles or single vacuum will belong to class N if they are not validated for special production determined by the manufacturer.
All sterilizers (re-)sterilizing medical products are medical devices (MPs) and are classified as 2b in the Medical-Device-Directive (MDD).

EN 14180 Low temperature steam-formaldehyde sterilizers
Requirements and testing methods
EN 1422 Ethylene oxide sterilizers – Requirements and testing methods
EN ISO 18472 Resistometer (Test sterilizer) for biological and chemical indicators
DIN 58951 Steam sterilizers for laboratories - Part II: Requirements

European Norms (EN) and/or International Standards (ISO) for sterilizers, packaging material, sterilization monitoring and validation

8. ISO 11737 Microbiological methods

Part I	Estimation of population of micro-organisms on products
Part II	Tests of sterility performed in the validation of a sterilization process

ISO 10993 Biological evaluation of medical devices

Part I	Selection of test
Part II	Animal welfare requirements
Part III	Tests for genotoxicity, carcinogenicity and reproductive toxicity
Part IV	Selection of tests for interactions with blood
Part V	Tests for cytotoxicity: in vitro methods
Part VI	Tests for local effects after implantation
Part VII	Ethylene oxide sterilization residuals
Part VIII	Clinical investigation
Part IX	Degradation of materials related to biological testing
Part X	Tests for irritation and sensitization
Part XI	Tests for systemic toxicity
Part XII	Sample preparation and reference material
Part XIII	Identification and quantification of degradation products from polymeric medical devices
Part XIV	Identification and quantification of degradation products from ceramics
Part XV	Identification and quantification of degradation products from metals and alloys
Part XVI	Toxicokinetic study design for degradation products and leachables
Part XVII	Establishment of allowable limits for leachable substances