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**

04/2008
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 Requirements for the development, validation and routine control (replaces EN 554)
Part I Requirements
Part II Guidance

EN ISO 11135 Requirements for the development, validation and routine control (replaces EN 550)
Part I Requirements
Part II Guidance

EN ISO 11137 Radiation sterilization (replaces EN 552)
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

04/2008
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:

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

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

04/2008