International and European Standardization of Sterilization Processes and Equipment
### Standards for sterilization in health care settings

<table>
<thead>
<tr>
<th>EN (16)</th>
<th>EN ISO (29)</th>
<th>ISO (3)</th>
</tr>
</thead>
</table>
| **EN ISO 17664**, Information for reprocessing | **EN ISO 14937**, Sterilization, general  
**EN ISO 11135-1** and **-2**, EO  
**EN ISO 17665-1** and **-2**, Moist heat  
**EN ISO 25424**, LTSF sterilization | **ISO/TS 11139**, Definitions |
| **EN ISO 14937**, Sterilization, general  
**EN ISO 11135-1** and **-2**, EO  
**EN ISO 17665-1** and **-2**, Moist heat  
**EN ISO 25424**, LTSF sterilization | **ISO/TS 17665-3**, Product families |
| **EN 556-1** and **-2** „STERILE“ | **EN ISO 15883-1** to **-7**, Washer-disinfector |
| **EN 285**, Large steam sterilizer  
**EN 1422**, EO sterilizer  
**EN 13060**, Small steam sterilizer  
**EN 14180**, LTSF Sterilizer  
**EN 16442**, Storage cabinet | **EN ISO 11140-1**, -3 and -4, Chem. Indicators  
**EN ISO 15882**, Guidance chem. Indicators  
**EN ISO 17664**, Information for reprocessing | **ISO 11140-5**, Chemical indicators |
| **EN 868-2** to **-9**, Packaging | **EN ISO 11607-1** and **-2**, Packaging  
**ISO/TS 16775**, Packaging | |
| **EN 867-5**, Chem. Indikators | **EN ISO 11138-1** to **-6**, Biological Indicators  
**EN ISO 14161**, Guidance biolog. Indicators | |
| **EN ISO 15883-1** to **-7**, Washer-disinfector | **EN ISO 15882**, Guidance chem. Indicators | |
| **EN ISO 18472**, Resistometer | **EN ISO 11135-1** and **-2**, EO  
**EN ISO 17665-1** and **-2**, Moist heat  
**EN ISO 25424**, LTSF sterilization | |

**Process standards include characterization of equipment, and testing of equipment.**
Standardization bodies

European Union
Mandate (content and timeframe) to CEN to draft standard,
fulfilment of harmonized standard provides presumption of conformity with essential requirements of EU Directives and Regulations

Harmonization if the content and the references comply with the mandate

CEN / CENELEC

World Trade Organization (WTO)
Agreement to prevent technical Barriers to Trade (TBT/1994)
Primacy of international standards.

ISO / IEC
(ISO/IEC Directives)

ISO / IEC

National Standardization Bodies, e.g.
BSI; DIN / DKE
In the framework of European standardization

National Standardization Bodies, e.g.
BSI; DIN / DKE; ANSI

Vienna and Dresden agreement

Standardization of Sterilization

WFHFF - Antalya, 2013-11-09
Ernst Dennhöfer
International standards are market-driven and support economic operators. Harmonized European standards are mandated and support legal acts, the free trade becoming a second-rate aim.

Route d) is an option proposed in ISO Global Relevance policy: ISO standard contains only core requirements, additional requirements are addressed through a separate EN in support of the core ISO standard.
The founding Principles of Standardization (WTO)

1. Transparency
Publication of work programme and draft standards, take comments into account in the further consideration of the standard.

2. Openness
Participation of all interested parties.

3. Impartiality and consensus
Take into account the views of all parties concerned and to reconcile any conflicting arguments.

4. Relevance and effectiveness
Aim-oriented response to regulatory and market needs, based on the state of the art; requirements based on principle of verifiability and performance rather than design or descriptive characteristics; for conformity assessment neutrality principle applies.

5. Coherence
Avoid conflicting international standards, duplication of, or overlap with.

6. Developing country interests
The overriding aim of a standard is to ensure fitness for purpose of the product concerned (aim-oriented approach) [ISO/IEC Directives].

An ISO standard should represent a single solution of global relevance:
- one concept,
- one definition,
- one specification,
- one verification procedure.

Avoidance of duplication is a general principle in the methodology of standardization.
Negative example:

“Risk” means:

- the combination of the probability of an event and its consequence;
  - **consequence** means positive or negative effect, e.g. on economic profit or loss, see ISO/IEC Guide 73 and ISO 31000, or

- a combination of the probability and the degree of an injury or damage to health that can arise in a hazardous situation, see Directive 2006/42/EC and ISO 12100, or

- combination of the probability of occurrence of harm and the severity of that harm;
  - **harm** means physical injury or damage to the health of people, or damage to property or the environment, see ISO/IEC Guide 51 and ISO 14971.
But:

A requirement that the values of a characteristic be stated by the manufacturer instead of specifying
the values themselves is not permissible in the case of health and safety requirements. [ISO/IEC
Directives]

Negative Example:

The minimum level of sterility assurance, SAL, to be achieved by the sterilization process on and/or
within a product shall be specified.
[ISO 17665-1, 8.2]

Positive example

The holding time shall be not less than 15 min, 10 min and 3 min for sterilization temperatures of
121 °C, 126 °C and 134 °C respectively.
[EN 285, 8.2.1.2.4]
The Elements of a standard (ISO/IEC Directives)

1) Scope
2) Introduction with aims of individual requirements
3) Normative references
4) Annex Z in harmonized EN

Information

Definitions
No other term and definition for that concept shall exist in another document (coherence).

Requirements
be comprehensible, consistent, accurate, identify the state of the art;
contain performance requirements, be not design restrictive.

Verification
Only such requirements shall be included as can be verified.

Guidance
Bibliography
Operating cycle

Cycle design according to load characteristics

- light superheat
- porous, air pocket
- hollow vacuum
- heavy condensate

definition of operating cycle performance 150 %

validation

routine operation performance up to 100 %
Inactivation of biological indicators (ISO 14161)

Surviving microorganisms

- Overkill - half-cycle
  - 1,000,000 spores
  - D = 1 min; F_BIO = 6 min

Bioburden:
100 – 100,000 microorganisms,
< 1 % with high resistance

Exposure time at 121 °C

\[ F_{BIO} = D_{121} \times \log N_0 \]

\[ F_{BIO} = \text{Bioindicator resistance} \]
\[ D_{121} = \text{D-value at 121°C} \]
\[ N_0 = \text{initial count} \]
\[ D\text{-value} = \text{time to achieve inactivation of 90 % of a population} \]

Extrapolation if straight survival curve

Biological indicator
ISO 11138-3
100,000 spores
D = 1.5 min

100,000 spores
D = 0.1 min

EN 285

Saturated steam
(121°+3)°C
15 min

Equilibration time 15 s

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WFHFF - Antalya, 2013-11-09
Ernst Dennhöfer
Purpose of sterilization in health care

Protection from health harm due to reprocessing of medical devices

Operators

Patients

Other persons

Cleaning

Kill

Drying

Generation of sterilizing agent

Transport of the sterilizing agent to the product

Inactivation of the microorganisms through the sterilizing agent

Control of steam quality

Control of steam penetration and condensation

Control of pressure, time and temperature
### Reproducibility of sterilization in health care

<table>
<thead>
<tr>
<th>Control function</th>
<th>ISO 17665</th>
<th>EN 285</th>
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<tbody>
<tr>
<td>Steam quality</td>
<td>See EN 285</td>
<td>Not normative, criteria in 13.3, tests in 21 and 23, contaminants in Annexes B, D</td>
</tr>
<tr>
<td>Cycle parameters</td>
<td></td>
<td>Required in 7 and 8, tests in 16 to 23</td>
</tr>
<tr>
<td>Process parameters</td>
<td>See Pharmacopoeias</td>
<td>Requirements in 7, criteria in 8.2.1, tests in 16 and 23</td>
</tr>
<tr>
<td>Steam penetration</td>
<td>Required in 12.1.6</td>
<td>Required in 8.1 and 8.2.2 test in 16, 17, (resp. 15) and 23 Indicator according ISO 11140-3, ISO 11140-4</td>
</tr>
<tr>
<td>Hollow</td>
<td></td>
<td>Required in 8.2.5, tests in 15</td>
</tr>
<tr>
<td>Light, superheat</td>
<td>Only “empty chamber” without criteria</td>
<td>Only “Antenna” in 8.1 and 8.2.1.2.2, test in 16</td>
</tr>
<tr>
<td>Heavy, condensate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fault recognition</td>
<td>See EN 285</td>
<td>Required in 7.2, tests missing, air detector in 8.2.4 (Option) Tests in 20 and 23</td>
</tr>
</tbody>
</table>
International standards support free trade.

European standards support legal requirements and free trade.

Users are not supported.