BS EN 13060:2014

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Small steam sterilizers

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National foreword

This British Standard is the UK implementation of EN 13060:2014. It supersedes BS EN 13060:2004+A2:2010 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization of Medical Devices.

A list of organizations represented on this committee can be obtained on request to its secretary.

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English Version

Small steam sterilizers

Petits stérilisateurs à la vapeur d'eau

Dampf-Klein-Sterilisatoren

This European Standard was approved by CEN on 15 November 2014.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN 13060:2014) has been prepared by Technical Committee CEN/TC 102 “Sterilizers for medical purposes”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2015 and conflicting national standards shall be withdrawn at the latest by December 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 13060:2004+A2:2010.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

The following amendments have been made in comparison with EN 13060:2004+A2:2010:

a) The scope of the standard has been revised with the aim to define small and large sterilizers on the chamber volume;

b) Normative references, terms and definitions have been updated, e.g.

   — term “hollow load A” has been changed to become “narrow lumen” (3.18)

   — term “hollow load B” has been changed to become “simple hollow items” (3.30)

c) In Clause 4 various sub-clauses and relevant requirements have been added, such as:

   — General requirements for design and construction (4.3.1),

   — Vibrations (4.3.5)

   — Noise (4.3.6)

   — Steam penetration test (4.5.1.6)

   — Software (4.5.4);

d) Sub-clause 4.8 has been divided into two subsections:

   — 4.8 Information to be provided

   — 4.9 Marking

e) Requirements in 5.3 on Attainment of the sterilization conditions have been revised;

f) Requirements in Clause 6 Safety, risk control and usability have been revised, e.g. requirements on electromagnetic compatibility (EMC), Pressure Equipment and risk control were added

g) Requirements on Sound power level (7.2.6) were added;

h) Requirements in 8.6 Porous load have been revised;

i) Requirements for Process challenge device (PCD) and chemical indicators for products with narrow lumen were revised;

j) Annex A has been revised, e.g. the defined hollow load A and B replaced by products with narrow lumen or simple hollow items;

k) Example for process challenge device for narrow lumen (PCD) has been moved to a new Annex G.

l) Annex ZA including Table ZA.1 on medical device directive and Table ZA.2 on machinery directive have been updated due to the changes made in the standard;

m) Standard has been editorially revised;

n) Updated Bibliography.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

Small steam sterilizers are widely used for medical purposes, e.g. in general medical practice, dentistry, podiatry, facilities for personal hygiene and beauty care and also veterinary practice. They are also used for materials and equipment which are likely to come into contact with blood or bodily fluids, e.g. implements used by beauty therapists, tattooists, body piercers and hairdressers. The specific nature of such sterilization loads used within these fields of application call for different performance requirements for the sterilization cycles and hence different corresponding test methods.

This European Standard specifies the general requirements for small steam sterilizers and associated test methods. Performance is defined by reference to standard test loads. These are used to define a basic minimum performance and are not necessarily related to specific medical devices. It is the responsibility of the user and the manufacturer of the device to be sterilized to determine that any particular cycle is suitable for sterilizing a particular device. The performance tests specified in this standard can also be used by the manufacturer of the device to be sterilized to specify the appropriate performance for decontamination processes according to the requirements for information to be given by medical device manufacturers according to EN ISO 17664. This will enable users to identify the specific sterilizer performance required to safely process their devices.

The performance requirements specified in this document are not intended for the process to be effective in inactivating the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob disease. However, some national regulations require the use of modified steam processes as part of a general prion decontamination programme.

It is essential that the sterilizer and associated equipment is used only for the sterilization of the type of products for which it is designed. The choice of sterilizer, sterilization cycle or quality of services provided can be inappropriate for a particular product. Therefore the suitability of a sterilization procedure for a particular product needs to be verified by validation (see EN ISO 17665-1).

1 Scope

This European Standard specifies the performance requirements and test methods for small steam sterilizers and sterilization cycles which are used for medical purposes or for materials that are likely to come into contact with blood or body fluids.

This European Standard applies to automatically controlled small steam sterilizers that generate steam using electrical heaters or use steam that is generated by a system external to the sterilizer.

This European Standard applies to small steam sterilizers used primarily for the sterilization of medical devices with a chamber volume of less than 60 l and unable to accommodate a sterilization module (300 mm × 300 mm × 600 mm).

The requirements concerning the quality management and risk management are addressed by other standards (e.g. EN ISO 13485, EN ISO 14971).

This European Standard does not apply to small steam sterilizers that are used to sterilize liquids or pharmaceutical products.

This European Standard does not specify safety requirements related to risks associated with the zone in which the sterilizer is used (e.g. flammable gases).

This European Standard does not specify requirements for the validation and routine control of sterilization by moist heat.

NOTE Requirements for the validation and routine control of sterilization by moist heat are given in EN ISO 17665-1.

This European Standard does not specify requirements for other sterilization processes that also employ moist heat as part of the process (i.e. formaldehyde, ethylene oxide).

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

prEN 285:2014[1)], *Sterilization — Steam sterilizers — Large sterilizers*

EN 285: 2006+A2:2009, *Sterilization — Steam sterilizers — Large sterilizers*

EN 867-5:2001, *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 Type B and Type S*

EN 868 (all parts), *Packaging for terminally sterilized medical devices* [2)]

EN 1041, *Information supplied by the manufacturer of medical devices*

EN 10088-1, *Stainless steels — Part 1: List of stainless steels*

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1) Under revision.

2) EN 868-1 has been replaced by EN ISO 11607-1.

EN 13060:2004+A2:2010, *Small steam sterilizers*

EN 13445 (all parts), *Unfired pressure vessels*

EN 60529, *Degrees of protection provided by enclosures (IP Code)(IEC 60529)*

EN 60751:2008, *Industrial platinum resistance thermometers and platinum temperature sensors (IEC 60751:2008)*

EN 61010-1:2010, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements (IEC 61010-1:2010)*

EN 61010-2-040:2005, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (IEC 61010-2-040:2005)*

EN 61326-1:2013, *Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 1: General requirements (IEC 61326-1:2012)*

EN ISO 228-1, *Pipe threads where pressure-tight joints are not made on the threads — Part 1: Dimensions, tolerances and designation (ISO 228-1)*

EN ISO 3746, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane (ISO 3746)*

EN ISO 4017, *Hexagon head screws — Product grades A and B (ISO 4017)*

EN ISO 4126-1, *Safety devices for protection against excessive pressure — Part 1: Safety valves (ISO 4126-1)*

EN ISO 11138-3, *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3)*

EN ISO 11140-1, *Sterilization of health care products — Chemical indicators — Part 1: General requirements (ISO 11140-1)*

EN ISO 14971:2012, *Medical devices — Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)*

EN ISO 17665-1:2006, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
active drain
drain through which fluids present in the chamber are discharged during the process

3.2
automatic controller
⟨sterilization⟩ device that, in response to cycle parameters, operates the apparatus sequentially through the operating cycle(s)

3.3
biological indicator
test system containing viable microorganisms providing a defined resistance to a specified sterilization process

[SOURCE: ISO/TS 11139:2006, definition 2.3]

3.4
calibration
set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realised by standards

[SOURCE: ISO/TS 11139:2006, definition 2.4]

3.5
chemical indicator
combination of the indicator agent and its substrate that reveals change in one or more process variables based on a chemical or physical change resulting from exposure to a process

Note 1 to entry: An indicator intended to be used only in combination with a specific test load is also termed an indicator (both together becoming an indicator system).

3.6
cycle parameter
physical value including its tolerances used for control, monitoring, indication and recording of the operating cycle

[SOURCE: prEN 285:2014, definition 3. 8, modified: “including its tolerances” was added]

3.7
double ended
with separate doors for loading and unloading

3.8
equilibration time
period which elapses between the attainment of the sterilization temperature in the usable chamber space and the attainment of the sterilization temperature at all points within the load

[SOURCE: EN ISO 17665-1:2006, definition 3.13, modified: ”at the reference measurement point” replaced by “in the usable chamber space”]

3.9
hazard
potential source of harm

[SOURCE: ISO/IEC Guide 51:1999, definition 3.5]

3.10
hazardous situation
circumstance in which people, property or the environment are exposed to one or more hazard(s)

[SOURCE: ISO/IEC Guide 51:1999, definition 3.6]

3.11
holding time
<small steam sterilizer> period for which the temperatures at all points within the useable chamber space and the load are continuously within the sterilization temperature band

Note 1 to entry: The holding time follows immediately after the equilibration time. The extent of the holding time is related to the sterilization temperature.

[SOURCE: EN ISO 17665-1:2006, definition 3.19, modified: “<small sterilizers>” added, ”at the reference measurement point and” deleted and “within the sterilization load” replaced by “within the usable chamber space and the load]

3.12
installation test
series of checks and tests performed during installation of the sterilizer in the place of use

3.13
instructions for use
instructions intended for the user (operator) of the sterilizer to enable safe and appropriate use

3.14
locked
with the locking device(s) fully engaged

3.15
maximum allowable pressure
maximum pressure for which the equipment is designed as specified by the manufacturer

Note 1 to entry: See Pressure Equipment Directive 97/23/EC, Article 1, sub-clause 2.3.

[SOURCE: EN 764-1:2004, definition 3.8, modified: addition of new Note 1 to entry]

3.16
medical device
any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury,

— investigation, replacement, modification or support of the anatomy or of a physiological process,

— supporting or sustaining life,

— control of conception,

— disinfection of medical devices,

— providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

[SOURCE: EN ISO 13485:2012, definition 3.7]

3.17
monitoring
checking against specifications

3.18
narrow lumen
hollow device which is beyond the range defined for a simple hollow item (see 3.30 and Figure A.3), and which is neither solid (see 3.32) nor porous (see 3.22)

Note 1 to entry: See Annex A.

EXAMPLES Long tubes, mating surfaces, hinged devices.

3.19
non-condensable gas
air and other gas which will not liquefy under the conditions of a saturated steam process

3.20
operating pressure
fluid pressure occurring during specified operating conditions

[SOURCE: EN 764-1:2004, definition 3.6]

Note 1 to entry: For the purposes of steam sterilization operating pressure is specified for the plateau period of a sterilization cycle.

3.21
plateau period
equilibration time plus the holding time

[SOURCE: prEN 285:2014, definition 3.23]

3.22
porous
permeable to water, air or other fluids

3.23
pre-purchase information
information necessary for prospective purchasers to enable them to make an informed purchasing decision

3.24
pressure vessel
housing and its direct attachments up to the coupling point connection it to other equipment, designed and built to contain fluids under pressure

Note 1 to entry: A vessel can be composed of more than one chamber.

[SOURCE: prEN 285:2014, definition 3.25]

3.25
process challenge device
PCD
item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process

[SOURCE: ISO/TS 11139:2006, definition 2.33]

3.26
reference measurement point
point where the temperature sensor used for the operating cycle control is located

[SOURCE: prEN 285:2014, definition 3.26, modified: "probes" replaced by "sensor"]

3.27
risk assessment
overall process comprising a risk analysis and a risk evaluation

[SOURCE: EN ISO 14971:2012, definition 2.18]

3.28
risk control
process through which decisions are reached and protective measures are implemented for reducing risks to, or maintaining risks within, specified levels

[SOURCE: EN ISO 14971:2012, definition 2.19, modified; “in” replaced by “through” and “made and measures” replaced by “reached and protective measures are]

3.29
saturated steam
water vapour in a state of equilibrium between its liquid phase and its gas phase

[SOURCE: EN ISO 17665-1:2006, definition 3.44, modified – “condensation and evaporation” replaced by “its liquid phase and its gas phase”]

3.30
simple hollow item
single-ended open-space items where the ratio of length to diameter of the cavity is greater than or equal to 1 and less than/or equal to 5 ($1 \leq L/D \leq 5$) and where the diameter is greater than or equal to 5 mm ($D \geq 5$ mm) or double-ended open-space items where the ratio of length to diameter of the cavity is greater than/or equal to 2 and less than/or equal to 10 ($2 \leq L/D \leq 10$) and where the diameter is greater than or equal to 5 mm ($D \geq 5$ mm)

Note 1 to entry: See Annex A.

EXAMPLES Bowls, receivers.

3.31
small steam sterilizer
steam sterilizer which has a chamber volume of less than 60 litres and is unable to accommodate a sterilization module

3.32
solid
product that is not made from porous material and which has no recesses or features which present a greater or equal challenge to steam penetration than a simple hollow item

3.33
sterile
free from viable microorganisms

[SOURCE: ISO/TS 11139:2006, definition 2.43]

3.34
sterile barrier system
minimum package that prevents ingress of microorganisms and allows aseptic presentation of product at the point of use

3.35
sterilization
validated process used to render a product free from viable microorganisms

Note 1 to entry: In a sterilization process the nature of microbial inactivation is described by an exponential function. Therefore the presence of a viable microorganism on any individual item can be expressed in terms of probability. This probability can be reduced to a very low number, it can never be reduced to zero.

[SOURCE: ISO/TS 11139:2006, definition 2.47, modified: Note 1 to entry was added]

3.36
sterilization cycle
operating cycle performed by a sterilizer for the purpose of sterilization

3.37
sterilization cycle type
classification of a sterilization process based on the performance of the cycle

Note 1 to entry: For types of sterilization cycles see Table 1.

Table 1 — Types of sterilization cycles

Type	Description of intended use
B	The sterilization of products as represented by the test loads in the standard. For products that lie within the limits specified for the relevant test loads, this includes solid products, porous products and lumen devices, wrapped (single- and multiple-layer) or non-wrapped.
N	The sterilization of non-wrapped solid products.
S	The sterilization of products as specified by the manufacturer of the sterilizer including non-wrapped solid products and at least one of the following: porous products, small porous items, lumen devices, bowls and receivers, single-layer wrapped products, multiple-layer wrapped products
NOTE 1 The description identifies ranges of products and test loads.	
NOTE 2 Non-wrapped sterilized instruments are intended for immediate use.	
NOTE 3 These categories are demonstrated by compliance with relevant tests listed in this standard.	

3.38
sterilization load
product to be, or that has been, sterilized together using a given sterilization process

[SOURCE: ISO/TS 11139:2006, definition 2.48]

3.39
sterilization module
rectangular parallelepiped of dimensions 300 mm (height) × 600 mm (length) × 300 mm (width)

[SOURCE: prEN 285:2014, definition 3.33]

3.40
sterilization process fault
one or more of the cycle parameters lying outside of its/their specified tolerance(s)

3.41
sterilization temperature
minimum temperature on which the evaluation of the sterilization efficacy is based

[SOURCE: prEN 285:2014, definition 3.35]

3.42
sterilization temperature band
temperature range the minimum of which is the sterilization temperature

Note 1 to entry: These temperatures are usually stated in whole degrees Celsius.

[SOURCE: prEN 285:2014, definition 3.36]

3.43
sterilizer
apparatus designed to deliver an operating cycle for the purpose of sterilization

[SOURCE: prEN 285:2014, definition 3.37]

3.44
sterilizer chamber
part of the sterilizer which receives the sterilization load

[SOURCE: EN ISO 17665-1:2006, definition 3.56]

3.45
technical information
information provided for installation, maintenance and use

3.46
theoretical steam temperature
temperature of saturated steam expressed in Kelvin, calculated from the measured pressure, using Equation (1):

$$T = A + B\,(\ln P + C)^{-1} \quad (1)$$

where

T is the theoretical steam temperature in Kelvin;

P is the measured pressure in megapascals, time averaged to result in a time constant between 1 s and 2,5 s;

A is 42,677 6 K;

B is –3 892,70 K;

C is –9,486 54

[SOURCE: IRVINE TH. F., LILEY, P.E., Steam and Gas tables with computer equations. Academic Press, 1984]

3.47
type test
series of checks and tests for a particular design of sterilizer

[SOURCE: prEN 285:2014, definition 3.39]

3.48
unloading door
door in a double ended machine through which the load is removed from the chamber after processing

3.49
usable chamber space
defined space within the equipment chamber, which is not restricted by fixed or mobile parts and which is available to accept the load

3.50
validation
<software> confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

[SOURCE: ISO 9000:2005, definition 3.8.5, modified: “<software>” added]

3.51
validation
<sterilization> documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications

[SOURCE: ISO/TS 11139:2006, definition 2.55: modified – “<sterilization>” added]

3.52
verification
confirmation through the provision of objective evidence that specified requirements have been fulfilled

[SOURCE: ISO 9000:2005, definition 3.8.4]

3.53
water charge
volume of the water in the vessel from which the steam for the sterilization cycle is generated

3.54
works test
series of tests performed during or after manufacture to demonstrate compliance of each equipment with the requirements of the test specified

[SOURCE: prEN 285:2014, definition 3.44]

3.55
wrapped
enclosed within a package (sterile barrier system)

Note 1 to entry: In this standard the sterile barrier system can be a single layer sterile barrier system.

4 General technical requirements

4.1 Dimensions

The sterilizer shall have a chamber volume less than 60 l and be unable to accommodate a sterilization module (300 mm x 300 mm x 600 mm).

4.2 Materials

The materials used for components in contact with steam, including instrumentation, shall:

— resist the attack of steam and condensate,

— not lead to deterioration of the quality of the steam.

Any material used shall not release any substance in such quantities that it could constitute an environmental or health risk.

NOTE Because of the different types of sterilizers and the large number of uses, it is not possible to specify detailed requirements for materials for specific applications.

4.3 Design and construction

4.3.1 General

4.3.1.1 Transport, storage and packaging conditions for which the device is designed and manufactured shall be specified to ensure its characteristics and performance for intended use are not adversely affected.

4.3.1.2 The sterilizer package should be designed to protect the sterilizer and preserve its characteristics during intended transport and storage.

4.3.1.3 The sterilizer and its components (if applicable) shall be packed for transportation and storage in a way that, when handled or transported, all parts of the sterilizer shall remain in their position and orientation so that the sterilizer remains stable and no moving part can cause a hazard.

4.3.1.4 Where the weight, size or shape of the sterilizer or its various components prevents them from being moved by hand, the sterilizer, or each component shall either be fitted with attachments for lifting gear, or be designed so that it can be fitted with such attachments, or be shaped in such a way that standard lifting gear can easily be attached for safe handling.

4.3.1.5 The design and construction of the device shall be such as to avoid errors in connection, fitting, refitting or direction of movement of internal and external parts or devices, which could be a source of risk. Should this not be possible, information on connection, fitting, refitting and direction of movement shall be given on/by the parts.

4.3.2 Doors and locking devices

4.3.2.1 Doors and locking devices shall be designed according to EN 61010-2-040:2005, 7.101.

4.3.2.2 The door shall be capable of being closed without being locked, so that it can be re-opened and closed before a sterilization cycle is initiated.

When the door is fully closed, it shall be in the position required for it to be locked.

When the door is locked, separate actions shall be required to unlock and to open the door.

4.3.2.3 When fitted, the door seal shall permit ease of cleaning of the contact surfaces and seal replacement.

4.3.2.4 After cycle start it shall not be possible to open a sterilizer door before "cycle complete" is indicated, except through special intervention that will lead to a "sterilization process fault" indication.

4.3.2.5 For double ended sterilizers it shall not be possible for more than one door to be open at a time, except for maintenance purposes.

4.3.2.6 For double ended sterilizers it shall not be possible to open the unloading door before "cycle complete" is indicated.

4.3.3 Test connection(s)

4.3.3.1 The sterilizer shall be equipped with at least one standard test connection.

4.3.3.2 The test connection(s) shall have a female pipe thread conforming to G1/4 according to EN ISO 228-1.

4.3.3.3 The test connection(s) shall be at a point of easy access to the chamber. The test connection(s) shall be clearly marked.

4.3.3.4 The steam inlet or vacuum ports and pipelines shall not be used for test connections.

4.3.4 Air filter

4.3.4.1 The air admitted to return the sterilizer chamber to atmospheric pressure after a vacuum drying stage shall be admitted through a filter.

4.3.4.2 Air filters shall be constructed from materials compatible with steam sterilization.

4.3.4.3 The filter unit shall be readily accessible.

4.3.4.4 The filter shall be protected from any influence that can impair its proper function.

4.3.4.5 The filter shall retain not less than 99,5 % of particles greater than 0,30 µm.

4.3.5 Vibrations

4.3.5.1 The design of the sterilizer shall limit vibrations to a level that does not impair the performance of the device nor cause an unacceptable health risk for any person.

4.3.5.2 Means shall be incorporated to reduce vibrations generated by components of the sterilizer, taking account of available solutions for reducing vibrations at source.

4.3.5.3 If vibrations can cause a loss of stability of the sterilizer, means shall be provided for suitable fixation.

4.3.6 Noise

4.3.6.1 Means shall be incorporated to reduce noise generated by components of the sterilizer, taking account of available solutions for reducing noise at source.

4.3.6.2 The sound power levels as required by 7.2.6 shall be stated in the documentation (see Table 4, item nr. 22).

4.4 Instrumentation, indication and registration devices

4.4.1 General

All instruments and indicating devices specified in 4.4 shall be located where they can be viewed readily by the operator under normal operation of the sterilizer and their function shall be identified.

Unless otherwise specified in this standard, the required instruments and gauges shall be readable by normal or corrected vision from a distance of 1 m and with a minimum illumination of (215 ± 15) lx.

4.4.2 Instruments and indicators

4.4.2.1 General

Sterilizers shall be provided with the following instruments:

a) sterilizer chamber temperature indicating instrument;

b) sterilizer chamber pressure indicating instrument;

c) jacket pressure indicating instrument (if the sterilizer is fitted with a pressurized jacket).

NOTE National or international regulations can apply.

4.4.2.2 Sterilizer chamber temperature indicating instrument

The chamber temperature indicating instrument shall:

a) be either digital or analogue;

b) be graduated in degrees Celsius;

c) have a scale which includes 75 °C to 150 °C;

d) have an accuracy of better than ± 2 °C over the scale range 75 °C to 150 °C;

e) for analogue instruments, be graduated in divisions not greater than 2 °C;

f) for digital instruments, have a resolution better than 1 °C;

g) be adjusted to an accuracy of +0 °C/–1,5 °C at the sterilization temperature;

h) when used for a control function, have a broken sensor protection that fails to safety;

i) have an ambient temperature error compensation not exceeding 0,04 K/K over the scale range;

j) have means of adjustment *in situ* by the use of a special tool, key or code without dismantling the instrument;

k) have a response time τ_{90} ≤ 5 s when tested according to EN 60751:2008, 6.5.2.

4.4.2.3 Sterilizer chamber pressure instrument

The sterilizer chamber pressure instrument shall:

a) be either digital or analogue;

b) be graduated in kilopascals or bars;

c) when the sterilization cycle includes a vacuum phase, have a scale which includes the range 0 kPa and 1,3 times the maximum allowable pressure or –1 bar and 1,3 times the maximum allowable pressure, given as absolute pressure value with a zero reading at absolute vacuum or ambient pressure respectively;

d) when the sterilization cycle does not include a vacuum phase, have a scale which includes the range 100 kPa and 1,3 times the maximum allowable pressure or 0 bar and 1,3 times the maximum allowable pressure, given as absolute pressure value;

e) have an accuracy of better than or equal to ± 5 kPa (0,05 bar) over the scale range;

f) for analogue instruments, be graduated in divisions not greater than 20 kPa (0,2 bar);

g) for digital instruments, have a resolution of better than or equal to 2 kPa (0,02 bar);

h) when used for a control function, have a broken sensor protection that fails to safety;

i) have an ambient temperature error compensation not exceeding 0,04 %/K over the scale range;

j) when the sterilizer chamber pressure instrument is adjustable it shall require the use of a special tool, key or code.

4.4.2.4 Jacket pressure indicating instrument

If the sterilizer is fitted with a pressurized jacket, the jacket pressure indicating instrument shall:

a) be either digital or analogue;

b) be graduated in kilopascals or bars;

c) have a scale which includes the range 100 kPa and 1,3 times the maximum allowable pressure, or 0 bar and 1,3 times the maximum allowable pressure, given as absolute pressure value;

d) have an accuracy of better than or equal to ± 10 kPa (0,10 bar) over the scale range;

e) for analogue instruments, be graduated in divisions not greater than 20 kPa (0,2 bar);

f) for digital instruments, have a resolution of better than or equal to 10 kPa (0,1 bar);

g) when used for a control function, have a broken sensor protection that fails to safety;

h) have an ambient temperature error compensation not exceeding 0,04 %/K over the scale range;

i) when the jacket pressure indicating instrument is adjustable it shall require the use of a special tool, key or code.

4.4.3 Indicating devices

4.4.3.1 Loading side of the sterilizer

In addition to the instruments identified in 4.4.2.1, the loading side of the sterilizer shall be provided with indicating devices visible from the operating position providing at least the following information:

a) “door(s) locked”;

b) “in progress”;

c) “cycle complete”;

d) “sterilization process fault”;

e) sterilization cycle selected and the type of cycle according to this standard;

f) sterilization cycle counter (see 4.4.3.4).

The "cycle complete" indication shall be cancelled when the door-opening process has been initiated.

4.4.3.2 Double ended sterilizer

In addition to 4.4.3.1 the unloading side of a double ended sterilizer shall be provided with indicating devices visible from the operating position providing the following information:

a) sterilizer chamber pressure;

b) “doors locked”;

c) “in progress”;

d) “cycle complete”;

e) “sterilization process fault”.

The "cycle complete" indication shall be cancelled when the opening of the door has been initiated.

4.4.3.3 Acoustic signals

When fitted, the acoustic signal shall be time limited to a maximum of 30 s and/or it shall be possible to interrupt it.

4.4.3.4 Cycle counter

The cycle counter shall:

— indicate the total number of all cycles started;

— be capable of displaying a minimum of five digits with each digit making a full count of 0 to 9.

The cycle counter shall not be capable of being reset or altered by the user or operator.

4.4.3.5 Air leak indication

If the sterilizer utilizes a vacuum stage for air removal, it shall be equipped with an automated air leakage rate test cycle. This test cycle will operate between two pressures, one of which shall be equal to or lower than the lowest pressure during air removal and steam penetration considering all available sterilization cycles. An air leakage rate signified by a pressure change greater than 0,13 kPa/min (1,3 mbar/min) shall result in a "sterilization process fault" indication.

4.4.4 Recorders and recordings

4.4.4.1 General

4.4.4.1.1 Sterilizers shall be provided with a recorder independent from the control system. Alternatively a process evaluation system according to 4.4.5 shall be installed.

If the sterilizer is fitted with a process evaluation system, a registration unit for documentation of its results should also be fitted.

Recorders can be either analogue or digital, in-built or external or networked.

4.4.4.1.2 All data sampled during the sterilization cycle shall be represented in the record. Records shall be readable by normal or corrected vision from a distance of 250 mm and with a minimum illumination of (215 ± 15) lx.

4.4.4.1.3 The following parameters shall be recorded or, alternatively, evaluated by a process evaluation system according to 4.4.5:

— pressure, independent from the process controller, and the temperature signal taken from the process controller; or

— temperature, independent from the process controller, and the pressure signal taken from the process controller;

— time, independent from the process controller or automatically verified to another source.

If a process evaluation system is used it shall comply with 4.4.5.

4.4.4.1.4 Analogue systems to be considered independent shall be completely separate. Digital systems to be considered independent shall have separate sensors, amplifiers and AD converters.

If in addition a process evaluation system is used, independence is not required.

4.4.4.1.5 Time records shall have a measurement error not exceeding 1 % of a defined time interval of the operating cycle.

Time records should be graduated in hours, minutes and seconds as applicable.

4.4.4.2 Recorders producing analogue records

4.4.4.2.1 Temperature and pressure shall be recorded on the same chart with the same time scale.

4.4.4.2.2 For recorders producing analogue records a time scale of not less than 4 mm/min shall be used.

If times are marked, units shall be either in seconds or minutes or multiples thereof.

4.4.4.2.3 Temperature recorders producing analogue records shall:

a) have a chart graduated in degrees Celsius;

b) have a chart graduated in divisions not greater than 2 K;

c) have a scale which includes the range 50 °C to 150 °C;

d) have an accuracy of ± 1 % or better over the scale range 50 °C to 150 °C;

e) have a resolution of 1 K or better;

f) have the means to be adjusted within ± 1 K at the sterilization temperature;

g) sample each channel at least once every 2,5 s;

h) print data from each channel at least once 2,5 s.

4.4.4.2.4 Pressure recorders producing analogue records shall:

a) have a chart graduated in kilopascals or bars;

b) have a scale which includes 0 kPa to 400 kPa (–1 bar to 3 bar);

c) indicate zero either at absolute vacuum or at ambient pressure respectively;

d) have an accuracy of ± 1,6 % or better over the scale range 0 kPa to 400 kPa (–1 bar to 3 bar);

e) when the sterilization cycle does not include a vacuum phase, have a scale which includes 100 kPa to 400 kPa (0 bar to 3 bar);

f) when the sterilization cycle does not include a vacuum phase, have an accuracy of ± 1,6 % or better over the scale range 100 kPa to 400 kPa (0 bar to 3 bar);

g) sample each channel at least once every 2,5 s;

h) print data from each channel at least once every 2,5 s;

i) have a chart with graduated divisions not greater than 20 kPa (0,2 bar);

j) have a resolution of 5 kPa (0,05 bar) or better;

k) be adjusted to an accuracy of ± 5 kPa (±0,05 bar) or better at the operating pressure.

In case the sterilization temperature is higher than 134 °C the scale for pressure recording systems shall be extended accordingly.

4.4.4.3 Recorders producing digital records

4.4.4.3.1 Not all data sampled to produce a digital record needs to be printed but, the minimum recording shall include at least the information according to Table 2 for the specimen sterilization cycle in Figure 1.

4.4.4.3.2 Temperature recorders producing digital records shall:

a) have alpha numeric characters;

b) have data identified by text or symbols or both;

c) have the data presented as text or figures or both;

d) have a paper width which has a space for a minimum of 15 characters per line;

e) have a range which includes 50 °C to 150 °C;

f) have an accuracy of ± 1 % or better over the range 50 °C to 150 °C;

g) have the means to be adjusted within ± 1 K at the sterilization temperature;

h) have a resolution of 0,1 K or better;

i) sample each channel at least once every 2,5 s.

4.4.4.3.3 Pressure recorders producing digital records shall:

a) have alpha numeric characters;

b) have data identified by text or symbols or both;

c) have the data presented as text or figures or both;

d) have a paper width which has a space for a minimum of 15 characters per line;

e) have a range which includes 0 kPa to 400 kPa (–1 bar to 3 bar);

f) when the sterilization cycle does not include a vacuum phase, have a scale which includes 100 kPa to 400 kPa (0 bar to 3 bar);

g) have an accuracy of ± 1,6 % or better over the range 0 kPa to 400 kPa (–1 bar to 3 bar);

h) when the sterilization cycle does not include a vacuum phase, have an accuracy of ± 1,6 % or better over the scale range 100 kPa to 400 kPa (0 bar to 3 bar);

i) be adjusted to an accuracy of better than or equal to ± 5 kPa (±0,05 bar) at the operating pressure;

j) sample each channel at least once every 2,5 s;

k) have a resolution of 1 kPa (10 mbar) or better.

In case the sterilization temperature is higher than 134 °C the scale for pressure recording systems shall be extended accordingly.

Table 2 — Data and limiting values to be recorded

Programme step	Time	Temperature (measured value)	Pressure (measured value)	Sterilization programme[c]	Cycle No.	Date and sterilizer identification
1	x			x	x	x
$t_{1, 3, 5}$	x		x[b]			
$t_{2, 4}$	x		x[b]			
t_6	x	X	x			
t_s	x[a]	x[d]	x[d]			
t_7	x	x	x			
t_8	x		x			
t_9	x		x			
2	x					

1 START - start of the operating cycle

$t_{1, 3, 5}$ time for vacuum pulse

$t_{2, 4}$ time for pressure pulse

t_6 sterilization start time

t_s holding time

t_7 sterilization end time

t_8 drying start time

t_9 drying end time

2 END - end of operating cycle ("cycle complete", see 4.4.3.2)

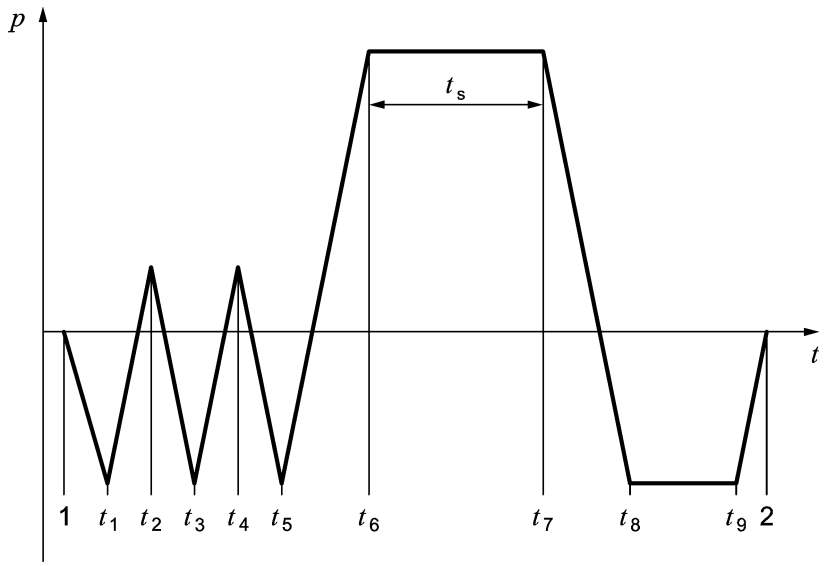
a Optional.

b Maximum or minimum achieved.

c If the sterilizer is provided with different cycles.

d The highest and the lowest values of both, the pressure and the temperature prevailing during the holding time shall be printed unless these values are not evaluated by a process evaluation system according to 4.4.5.

NOTE For explanation see also Figure 1.



Key

1	START - start of the operating cycle
$t_{1, 3, 5}$	time for vacuum pulse
$t_{2, 4}$	time for pressure pulse
t_6	sterilization start time
t_s	holding time
t_7	sterilization end time
t_8	drying start time
t_9	drying end time
2	END - end of operating cycle ("cycle complete", see 4.4.3.2)

Figure 1 — Diagram of a specimen sterilization cycle (given as an example only)

4.4.5 Process evaluation system

4.4.5.1 If fitted the process evaluation system shall:

a) compare with a validated cycle any change in pressure and temperature and the period of the cycle during which the change occurs; any change beyond programmed limits shall cause a "sterilization process fault" to be indicated;

b) compare two independent temperature sensors, which may be those associated with the sterilizer chamber temperature indicating instrument and the temperature recorder; or

c) be capable of comparing the theoretical steam temperature with the chamber temperature during the holding time;

d) have a temperature measuring system accuracy better than or equal to that specified for the chamber temperature indicating instrument;

e) have a pressure measuring system accuracy better than or equal to that specified for the chamber pressure indicating instrument;

f) have a time measuring system with an accuracy of ± 1 % or better;

g) operate to the specified limits taking into account the process evaluation system accuracy;

h) have been verified for its intended reaction upon specified process failures.

4.4.5.2 If a recorder is fitted to the process evaluation system, the following data shall be recorded:

— sterilizer identification;

— date;

— program;

— cycle number;

— process satisfactory, or not satisfactory.

NOTE See Annex B for additional information on process evaluation systems.

4.5 Control systems

4.5.1 Process control

4.5.1.1 The sterilization process can be either temperature or pressure controlled. In both cases the process control system shall ensure the presence of saturated steam.

4.5.1.2 The sterilizer shall be provided with an automatic controller. The automatic controller shall be programmed with the pre-set cycle parameters for each stage of the sterilization cycle. It shall not be possible to change cycle parameters during a cycle. The pre-set cycle parameters shall only be adjustable by use of a special key, tool or code. The automatic controller shall be capable of monitoring the specified pre-set cycle parameters.

4.5.1.3 For a double ended sterilizer the controls used to start the sterilization cycle shall be located on the loading side of the sterilizer.

4.5.1.4 If the sterilizer is designed to retain water in the chamber after completion of the cycle, the visual indication “cycle complete” shall be activated only if the water will not boil at the moment of unsealing the door (see 4.4.3) and there is no retained pressure in the chamber’.

4.5.1.5 Means shall be provided for the operator to terminate the sterilization cycle without causing a hazardous situation. When the sterilization cycle is terminated by the operator, a "sterilization process fault" shall be indicated.

4.5.1.6 A separate test cycle shall be provided if the exposure time specified for the indicator used to determine the efficacy of steam penetration is different than the plateau period used for the sterilization cycle used for production. This cycle shall have the same air removal stage as the one used for the sterilization cycle used for production.

NOTE Indicators are specified in EN 867–5:2001, 4.2, 4.3 and 4.4.

4.5.2 Performance verification

It shall be possible to assess the performance of an operating cycle:

— from readings noted from the sterilizer indicators and;

— from readings obtained from a recorder; or

— automatically by a process evaluation system.

4.5.3 Sterilization process fault indication systems

4.5.3.1 The values for all cycle variables shall be specified. These shall include, but are not limited to:

— the switch points of all vacuum and steam pressure pulses,

— the sterilization pressure and temperature, and

— the holding times related to the available sterilization cycles (see 4.8.2).

4.5.3.2 The automatic controller shall cause a visual indication that a "sterilization process fault" has occurred and not cause a hazardous situation, if:

— the values of cycle variables are outside the specified limits;

— a power failure occurs;

— a failure of a service occurs.

NOTE This is sufficient to prevent the attainment of the values specified for the variables.

4.5.3.3 If the sterilizer is fitted with a printer for recording cycle parameters, the indication of a "sterilization process fault" shall also be printed.

4.5.3.4 After a "sterilization process fault" has been indicated, the automatic controller shall allow the sterilization cycle to be terminated without causing a hazardous situation. To make the sterilizer ready for use again the use of a special tool, key or code shall be required.

4.5.3.5 A visual display of a "sterilization process fault" shall continue at least until an action different from the normal operation of the sterilizer is carried out to reset the system.

4.5.3.6 For double ended sterilizers, a "sterilization process fault" shall be indicated at both ends and it shall not be possible to open the unloading door if a "sterilization process fault" is indicated (see also 4.4.3.2).

4.5.4 Software

4.5.4.1 Software for automatic controllers shall be demonstrated to function as intended.

4.5.4.2 Classification of software with respect to safety shall be established through risk assessment.

4.5.4.3 Software parts related to safety of patients, users or any other persons shall be verified and validated using methods according to the state of art. The methods used in the validation and verification process shall be justified and documented.

NOTE EN 61508 (series), EN 62304 and EN 62061 support activities to be performed.

4.6 Process

4.6.1 General

For moist heat sterilization using steam as the sterilant it is essential that all surfaces to be sterilized are subjected to saturated steam at a predetermined temperature for a predetermined period of time. Proper

steam penetration into the load and — if applicable into the individual items — therefore is essential. Steam penetration requires adequate air removal. The requirements listed below and the associated test methods address factors and parameters that may promote or inhibit steam penetration and therefore the efficacy of the sterilization process.

4.6.2 Sterilization temperature, sterilization temperature band, holding time

The sterilization temperature, the sterilization temperature band and the holding time shall be pre-set, specified and stated in the user instructions (see 4.8.3) for each available sterilization cycle.

4.6.3 Time-temperature relationships

The sterilizer shall provide sterilization conditions according to, or alternatives which can be proven to be equivalent to, the time temperature relationships given in Table 3.

In case the sterilization temperature is higher than 134 °C the scale for pressure recording systems shall be extended accordingly.

Table 3 — Time-temperature relationships for sterilization conditions [4]

Sterilization temperature °C	**Minimum holding time** min
121	15
126	10
134	3
143	1

4.6.4 Equilibration time

The equilibration time shall not exceed 15 s.

An equilibration time not exceeding 30 s is acceptable if:

— the rise of the theoretical steam temperature during the last 10 K of the heating stage is less than 8 K/min but greater than 1 K/min;

— during the last 10 K of the heating stage all temperatures measured in the chamber and the load as well as the theoretical steam temperature do not differ from one another by more than 2 K.

4.7 Services and local environment

4.7.1 General

Sterilizers shall be designed to comply with the requirements of this standard when operated under the environmental conditions for the equipment.

NOTE The performance of a sterilizer is dependent on its design and construction, together with the quality of services and other conditions at its place of installation.

4.7.2 Electrical supply

The sterilizer shall be designed to operate when the mains supply voltage is maintained within ± 10 % of the nominal supply voltage.

4.7.3 Water supply for steam generation in the sterilizer

4.7.3.1 The sterilizer shall be designed to function with water free from contaminants in a concentration that could impair the sterilization process or harm the sterilizer or the sterilization load.

NOTE Suggested maximum limits of some contaminants are given in Annex C.

4.7.3.2 If a water reservoir is fitted:

a) the reservoir and associated pipe work shall be fitted with a valve or other device to allow draining by the operator or the automatic control system;

b) the reservoir shall be large enough to contain sufficient water for the running of a complete sterilization cycle or the number of consecutive operating cycles specified to be performed with the test load having the maximum steam consumption;

c) the reservoir shall be vented and its design shall facilitate cleaning, inspection and filling;

d) means shall be provided to indicate whether the water in the reservoir is sufficient for an operating cycle;

e) the sterilizer shall not be capable of starting a cycle if there is insufficient water in the reservoir;

f) the water reservoirs shall be designed to prevent back siphoning.

4.7.4 Drains

The sterilizer shall be designed so that the temperature of water or vapour drained to an external drainage system does not exceed 100 °C.

4.7.5 Compressed air for control systems

When applicable the sterilizer shall be designed to operate with a compressed air supply, free of liquid water, filtered to 25 µm and free of oil droplets greater than 2 µm. The permissible air pressure range shall be stated.

4.7.6 Water used other than for steam generation

When water is used for cooling purposes and/or in a vacuum system the sterilizer shall be designed to be capable of operating with water which is of potable quality and supplied at a temperature in the range as specified, including 15 °C.

NOTE National regulations sometimes require a backflow protection device to be fitted.

4.7.7 External steam supply to the sterilizer

If used, the external steam supply to the sterilizers shall be in accordance with EN 285:2006+A2:2009, 13.3.

4.8 Information to be provided

4.8.1 General

The information given in the manuals shall be according to EN 1041.

Where necessary, further instructions shall be given on the potential risks related to incorrect connection, fitting, refitting parts or direction of movement.

The information shall be given in the language as required by applicable regulations at the installation site.

The information provided shall address the needs of users with different technical knowledge, education and training.

The information provided in Table 4 shall be provided as individual manuals or alternatively be combined, as deemed appropriate for delivery (see 4.8.2, 4.8.3, and 4.8.4).

4.8.2 Pre-purchase information

The information provided in the pre-purchase information column of Table 4 shall be provided upon demand.

NOTE This information is considered necessary for prospective purchasers to enable them to make an informed purchasing decision.

4.8.3 Instructions for Use

When the sterilizer is delivered, at least the information specified in the instruction manual column of Table 4 shall be provided and shall include the date of issue or the latest revision of the respective documents.

NOTE This information is considered necessary for the user (operator) of the sterilizer to enable safe and appropriate use.

4.8.4 Technical Information

When the sterilizer is delivered, at least the information specified in the technical information column of Table 4 shall be provided and shall include the date of issue or the latest revision of the respective documents.

NOTE This information is considered necessary for installation and maintenance of the sterilizer.

Table 4 — Minimum information to be provided

Nr °	Requirement	Instructions for Use	Technical Information	Pre-purchase information
1	Reference to this standard	x	x	x
2	A clear description of the intended use of the sterilizer	x	x	x
3	A general description of the sterilizer	x	x	x
4	Description of the available sterilization cycles	x	x	x
5	A specification and tolerances of the cycle parameters for the operating cycle		x	
6	The diagram of pressure vs. time and temperatures as specified in Table 2, for the operating cycle(s)	x	x	
7	Maximum total cycle time for the test loads as described in this standard	x	x	x
8	The type of sterilization cycles specified as B, N, or S and the corresponding types of loads that can be processed (see Annex D). When alternative test methods are used, see 7.1.	x	x	x
9	Ranges of products, load configuration and maximum total weight and, if relevant, maximum weight per item, loading weight per tray and/or basket and/or rack	x	x	x

Nr °	Requirement	Instructions for Use	Technical Information	Pre-purchase information
10	The configuration of available load support systems		x	
11	Instructions for handling during transport and storage such as conditions for stability, orientation, temperature, humidity and pressure		x	x
12	Installation information, including: - the overall dimensions of the sterilizer; - the overall mass of the sterilizer; - the weight load to the installation plane when the reservoir is filled with water and the chamber contains a maximum load; - the weight load to the installation plane when the reservoir is filled with water and the chamber or jacket is filled with water for a water pressure test, if such a test is required by pressure vessel regulations; - assembly, installation and connection instructions, including drawings, diagrams and the means of attachment, and the specified requirements for the installation area; - the drain connection, if applicable, not to cause back pressure or obstruction to flow; - the clearance required to allow opening of the door(s) and loading and unloading operation of the sterilizer; - if applicable, provisions necessary to ensure the mechanical stability of the device during installation, operation, maintenance and service.		x	x
13	Type of electricity supply, DC or AC, single- or poly-phase voltage, current and frequency	x	x	x
14	For external steam supply, if applicable: - the maximum and minimum supply pressure; - the maximum flow and usage rate.		x	x
15	For external water supply used: - the maximum and minimum pressure; - the flow rate at minimum pressure; - the maximum temperature; - the volume used by the sterilization cycle having the highest steam consumption; - the manufacturer's recommended quality.	x	x	x
16	For the water used during the process for steam generation: - the volume used by the sterilization cycle/load having the highest steam consumption. - the manufacturer's recommended quality NOTE Suggested maximum limits of some contaminants	x	x	x

Nr °	Requirement	Instructions for Use	Technical Information	Pre-purchase information
	are given in Annex C.			
17	The minimum water charge in the water reservoir	x	x	
18	The necessary frequency of draining the water reservoir, cleaning it and filling it with fresh water	x	x	
19	For compressed air, if applicable: - the maximum and minimum supply pressure; - the flow at minimum pressure; - quality information/requirement.		x	x
20	The maximum flow rate and temperature of any water drained and its maximum temperature		x	x
21	The total heat in Joules transmitted by the sterilizer to the surrounding air during an hour of continuous operation with the sterilization cycle giving the highest emission of heat, based on an ambient temperature of (23 ± 3) °C. NOTE Heat transmitted by the sterilizer and the sterilized load can affect design of ventilation systems for the installation area.		x	x
22	The sound power levels as required by 7.2.6.		x	x
23	Dimensions of the usable chamber space (see 3.48)	x	x	x
24	Allowed range for the ambient temperature, altitude, pressure and humidity	x	x	x
25	The business name and address of the manufacturer, and the name and address of the authorized representative in the Community in cases where the manufacturer does not have a registered place of business in the Community.	x	x	x
26	The designation and details necessary for the user to identify the equipment (e.g. model number)	x	x	x
27	Instructions on the protective measures to be taken by the users, including, where appropriate, the personal protective equipment to be provided	x		
28	A document setting out the contents of the EC declaration of conformity	x	x	x
29	Description of the controls and indicating devices	x	x	
30	Any actions in case of malfunction	x	x	
31	The residual risk and respective warnings	x	x	
32	Description and functions of safety devices	x	x	
33	The time and procedures required for the sterilizer to be ready for routine use after the power is switched on	x	x	
34	If the sterilizer is fitted with a recorder producing analogue records, a set of reference records of acceptable sterilization cycles, a list of the tolerances in pressure and temperature which are acceptable and	x	x	

Nr °	Requirement	Instructions for Use	Technical Information	Pre-purchase information
	instructions on how to read and interpret the records			
35	If the sterilizer is fitted with a recorder producing digital records a list of the acceptable upper and lower limits of the measured and printed values for temperature, pressure and time and instructions on how to interpret the printed data	x	x	
36	The maintenance interval or timetable	x	x	
37	A complete list of spare parts replaceable by the user	x	x	
38	A list of special tools necessary for user maintenance	x	x	
39	Procedure for each user maintenance task	x	x	
40	A list of technical service locations	x	x	
41	Specified cycle process switch points and limits for each setting fitted		x	
42	Electrical diagrams and circuits		x	
43	The fluid plans and circuits		x	
44	A complete list of spare parts		x	
45	Identification of non-user serviceable items		x	
46	Technical details on function and settings of safety devices		x	
47	The setting of the air detector, if fitted		x	
48	The positions of the highest and the lowest temperature in the chamber during empty chamber test		x	
49	The minimum period of time that printed records remain legible when using printing media provided or specified for the product	x	x	x

NOTE The information given in the Instructions for Use need not be repeated in Technical Information.

4.9 Marking

4.9.1 Marking of the pressure vessel

The pressure vessel shall be marked according to EN 61010-1:2010, Clause 5, as modified by EN 61010-2-040:2005, Clause 5.

NOTE Pressure devices are regulated by the Pressure Equipment Directive 97/23/EC.

4.9.2 Marking of the sterilizer and the packaging

4.9.2.1 Instructions for handling, unpacking, transport and storage shall be clearly indicated on the outside of the package.

NOTE National or European regulation can require specific information or use of harmonized symbols.

4.9.2.2 The sterilizer shall provide the following information, clearly visible from the operating position and using where appropriate, suitable standardised symbols (see e.g. ISO 15223-1 and EN 61010-1:2010, Clause 5):

a) identification of the function of the instruments and controls;

b) the residual risks warnings;

c) if appropriate indication of the water quality to be used.

4.9.2.3 An identification plate that is clearly visible shall be affixed to the sterilizer frame or body and shall bear the following information:

a) name and address of manufacturer and (if applicable) the legal entity responsible for introducing the product in the EU market;

b) name and address of the authorized representative in the Community in cases where the manufacturer does not have a registered place of business in the Community;

c) model/type identification;

d) serial number;

e) year of manufacture;

f) rated voltage;

g) current type;

h) rated frequency;

i) maximum current or power;

j) CE-mark, accompanied by the European registration number(s) of the notified body or bodies engaged for medical device and pressure equipment as applicable;

k) warning symbols.

4.10 Accessories

The sterilizer shall be equipped with chamber furniture equivalent to the type used in the type test and suitable means to remove the load from the chamber.

NOTE Further guidance on accessories is given in Annex E.

5 Performance requirements

5.1 General

An explanation and rationale for the performance requirements and the respective tests are given in Annex F.

5.2 Air leakage rate

If the sterilizer utilizes a vacuum stage for air removal in any sterilization cycle, the rate of air leakage into the sterilizer chamber during periods of vacuum shall not cause the rate of pressure rise to exceed 0,13 kPa/min (1,3 mbar/min) when tested in accordance with 10.2.

5.3 Attainment of the sterilization conditions

5.3.1 The presence of saturated steam in the usable chamber space and the load is deemed to have been achieved when, throughout the holding time, all temperatures measured in the usable chamber space and the load:

— are not lower than the sterilization temperature;

— are not more than 3 K above the sterilization temperature.

For products designed and placed on the market prior to publication of this edition of EN 13060 the 4K band as specified by EN 13060:2004+A2:2010, 5.3.1 may apply.

— Do not differ from each other by more than 2 K.

The theoretical steam temperature which is calculated from the measured pressure shall also be considered as a measured temperature.

NOTE The process requirements (e.g. air removal, heat-up time) differ for different types of load. See EN ISO 17665-1.

5.3.2 For narrow lumen and simple hollow items, the presence of saturated steam is deemed to be adequately demonstrated by satisfactory colour change in the chemical indicator system used, as specified for the indicator system (see 10.6.2, 10.7.2).

5.3.3 To justify the minimum performance requirements for sterilizers and sterilization of narrow lumen or simple hollow items according to this standard, PCDs as specified in 8.10 or 8.11, respectively, shall be used.

NOTE These PCDs are not necessarily related to specific medical devices.

5.3.4 For porous load tests only, during the plateau period the temperature, if measured within 50 mm above the test load, shall not exceed the temperature measured at the reference measurement point of the sterilizer chamber by more than 5 °C for the first 60 s and 2 °C for the remaining period.

5.4 Product compatibility

5.4.1 Dynamic sterilizer chamber pressure test

The rate of pressure change during any part of the sterilization cycle shall not exceed 10 bar/min for any 2 s interval when tested in accordance with 10.3.

5.4.2 Maximum allowable temperature

The temperature in the usable chamber space of the empty chamber shall not exceed the highest value of the temperature band when tested in accordance with 10.4.

5.5 Drying

5.5.1 For wrapped loads, any remaining moisture shall not lead to wet packages and shall not result in detrimental effects on the sterilization load. Any remaining water droplets on the inner side of the film of laminate pouch shall evaporate within 5 min of end of cycle.

5.5.2 The change in moisture content of the load shall comply with 5.5.3 and 5.5.4 respectively when “cycle complete” is indicated.

5.5.3 For a solid load the moisture content shall not exceed 0,2 % when tested in accordance with 10.11.

5.5.4 For a porous load the moisture content shall not exceed 1,0 % when tested in accordance with 10.12.

5.6 Microbicidal efficacy

Microbiological tests are optional. If performed, as specified in 10.15, 10.16, 10.17, 10.18, 10.19 or 10.20, the sterilized biological indicator or the sterilized inoculated carrier shall not show growth. The biological indicator positive controls shall show growth.

5.7 Non-condensable gases

When a non-condensable gas test is performed, as described in 10.14, the percentage ratio of the volume of non-condensable gases to the volume of condensate collected shall be not greater than 3,5 %.

6 Safety, risk control and usability

6.1 General requirements

If applicable for the purpose of this standard:

a) For marking and documentation sterilizers shall comply with EN 61010-1:2010, Clause 5, as modified by EN 61010-2-040:2005, Clause 5.

b) For the protection against electric shock sterilizers shall comply with EN 61010-1:2010, Clause 4 and Clause 6, Annex A, Annex B, Annex C, Annex D, Annex F, Annex H, Annex K, as modified by EN 61010-2-040:2005, Clause 6.

c) For the protection against mechanical hazards and hazards related to mechanical functions sterilizers shall comply with EN 61010-1:2010, Clause 4 and Clause 7, as modified by EN 61010-2-040:2005, Clause 4 and Clause 7.

d) For the protection against hazards due to mechanical resistance to shock and impact sterilizers shall comply with EN 61010-1:2010, Clause 4 (except 4.4) and Clause 8.

e) For the protection against the spread of fire sterilizers shall comply with EN 61010-1:2010, Clause 4 and Clause 9 (except 9.5), as modified by EN 61010-2-040:2005, Clause 4 and Clause 9.

f) For the protection against hazards in relation to equipment temperature limits and resistance to heat sterilizers shall comply with EN 61010-1:2010, Clause 4 and Clause 10, as modified by EN 61010-2-040:2005, Clause 4 and Clause 10.

g) For the protection against hazards from fluids sterilizers shall comply with EN 61010-1:2010, Clause 4 and Clause 11, as modified by EN 61010-2-040:2005, Clause 4 and Clause 11.

h) For the protection against radiation, including laser sources, sterilizers shall comply with EN 61010-1:2010, Clause 4, 12.1, 12.3 and 12.6.

i) For the protection against liberated gases, substances, explosion and implosion sterilizers shall comply with EN 61010-1:2010, Clause 4 and 13.2.2, as modified by EN 61010-2-040:2005, Clause 4, 13.1.102 and 13.101.6.

j) For the protection against hazards related to components sterilizers shall comply with EN 61010-1:2010, Clause 4 and Clause 14, as modified by EN 61010-2-040:2005, Clause 4 and Clause 14.

k) For the protection by interlocks sterilizers shall comply with EN 61010-1:2010, Clause 4 and Clause 15.

l) For the protection against hazards resulting from application sterilizers shall comply with EN 61010-1:2010, Clause 16.

m) For the protection against hazards in relation to safety for unfired pressure equipment and assemblies sterilizers shall comply with all parts of EN 13445 series and EN 764-7 that are appropriate.

NOTE Additional guidance is given in EN ISO 12100.

6.2 Requirements for EMC

Sterilizers shall comply with EN 61326-1:2013 regarding electromagnetic compatibility (EMC).

6.2.1 Sterilizers operating in areas intended for medical electrical equipment or in the vicinity of other sensitive equipment shall be regarded as class B equipment as specified by EN 61326-1:2013.

6.2.2 The immunity performance criteria selected shall ensure that sterilizer performance as specified by Clause 5 of this standard is met when exposed to disturbance phenomena of EN 61326-1:2013, Table 1.

6.3 Requirements for pressure equipment

6.3.1 Pressure vessels shall comply with all parts of EN 13445 series that are appropriate for safety purposes for pressure equipment.

Other pressure equipment standards may apply if equivalence with respect to safety is verified.

6.3.2 For sterilizers excluded from Pressure Equipment Directive 97/23/EC, the safety devices, or their relevant components shall:

a) be either fail-safe, have redundancy or be self-diagnostic;

b) be independent from other safety functions, unless the other safety functions are proven not to be affected by these safety devices or their relevant functions;

c) have a protection level of at least IP 31 according to EN 60529;

d) have safety valves complying with EN ISO 4126-1;

e) have safety valves for steam and compressed air provided with means for manual testing, which shall be arranged such that the valves can be lifted off their seats when operating under pressure.

When the Pressure Equipment Directive 97/23/EC is not applicable, national regulations can apply.

6.4 Requirements for risk control

6.4.1 Risk assessment and risk control for sterilizer design and software shall be performed following the procedures and requirements given in EN ISO 14971. Specific requirements and results shall be established and documented.

For products designed and placed on the market prior to publication of this edition of EN 13060 other standards may apply instead of EN ISO 14971.

NOTE EN ISO 12100 can provide further information.

6.4.2 Risk analysis shall address the specific sterilizer design and features. Measures taken for risk reduction shall consider aspects as user knowledge, experience, training, ergonomics and usability.

NOTE EN ISO 12100 or EN 61508–1 can provide further information.

7 Categories of tests

7.1 General

7.1.1 The tests given in this standard and listed in Table 5 are reference tests intended for use in demonstrating conformity with the performance requirements specified. They can be used in type tests, works tests, in validation tests, or in periodic and routine tests carried out by the user.

7.1.2 The tests shall be performed with the relevant load support system in place. Specifications of the water used for steam generation and other facilities shall meet the specifications for this sterilizer.

NOTE Annex F contains a rationale for the test methods.

7.1.3 For particular sterilizer concepts and/or specified medical devices, some tests or test loads could not be applicable for physical reasons. In such cases, alternative test procedures and/or specific test devices (e.g. PCD's) are necessary to demonstrate:

a) compliance with the requirements given in 5.3.1, or when this is not possible;

b) achievement of a sterile product (see EN 556-1) when tested in accordance with EN ISO 17665-1.

In case of such tests being applied, these shall be fully documented. The following information shall be included in the manual or the pre-purchase documentation:

— the rationale for the standard test requirements not being applicable;

— the identification of the medical devices for which the cycle is being qualified;

— if used, a full specification of alternative test procedures and/or specific test devices (e.g. PCD's) to enable third parties to reproduce these tests;

— the type test results.

7.2 Type tests

7.2.1 For each (available) sterilization cycle, the test equipment and test procedures for type tests as specified in Table 5 are deemed suitable in order to verify compliance with this standard. Any additional claim made for specific cycles shall be supported by appropriate tests. These tests shall be performed with one or more sterilizers manufactured according to the production specification.

7.2.2 If the sterilizer is connected to external services during these tests, the services shall comply with 4.7.

7.2.3 Sterilizers shall be considered to be of the same design and not require separate testing if they have:

a) the same number of doors in the same configuration;

b) all service connections into the sterilizer chamber in the same orientation;

c) the same control system with all sensors required in this standard located in the same positions and orientations;

d) the same sterilization cycles.

7.2.4 The following design variations shall not require separate type testing:

a) differences in the dimensions of the sterilizer chamber not greater than ± 10 % of the dimensions, with similar sterilizer chamber shapes;

b) increase of the plateau period within a sterilization cycle having the same sterilization temperature and the same air removal stage (see also 4.6.3);

c) any change of the design or sourcing of equipment, including chamber furniture, provided there is available documented evidence of validation of the design change to show that there is no adverse effect on the performance of the sterilizer which would affect compliance with this standard.

7.2.5 When sterilizer cycles are added or changed on an existing type tested sterilizer only these additional or changed cycles shall be type tested.

7.2.6 The A-weighted sound power level shall be determined and specified for each type of sterilizer in accordance with EN ISO 3746.

NOTE Other methods of demonstrated equivalence can be used.

7.3 Works test

7.3.1 For each (available) sterilization cycle, the test equipment and test procedures for works tests as specified in Table 5 are deemed suitable in order to verify compliance with this standard. Any additional claim made for specific cycles shall be supported by appropriate tests. These tests shall be performed with each sterilizer manufactured according to the production specification.

NOTE The tests specified in Table 5 have not been established for special product programmes that are outside the scope of this standard.

7.3.2 A works test is not required if an installation test is performed.

NOTE Works or installation tests are the final tests before the sterilizer is released for use.

7.3.3 If the sterilizer is connected to external services during the works test, these services shall comply with 4.7.

7.4 Installation tests

7.4.1 If the sterilizer is assembled at the user site, or is connected to external facilities which could impair the sterilization process (power excluded), the test equipment and test procedures for installation tests as specified in Table 5 are deemed suitable in order to verify compliance with this standard.

7.4.2 If an installation test is performed, a works test is not required.

NOTE Works or installation tests are the final tests before the sterilizer is released for use.

7.4.3 If the sterilizer is connected to external services during the installation test, these services shall comply with 4.7.

8 Test equipment

8.1 General

Test equipment shall be capable of producing a record of all data obtained, to be retained for the interpretation of results. It shall be established that measuring equipment works within specifications at the time of use.

Standardized test loads as specified in this standard are used for operation qualification (OQ) tests of a specific sterilizer or process. However, successful results of these tests cannot be considered to justify satisfactorily sterilization performance when applied to actual medical devices used in practice. Demonstration of sterilization performance is part of performance qualification (PQ) (see EN ISO 17665-1).

8.2 Temperature sensors

8.2.1 Temperature sensors shall be used to measure the temperature in locations specified in the tests described in this standard. All temperature sensors used during a measurement shall have the same performance specifications.

8.2.2 The temperature measured by all temperature sensors when immersed in a temperature source at a temperature within the sterilization temperature band, known within ± 0,1 K, shall not differ by more than 0,5 K.

8.2.3 The cross sectional area of any part of the sensor and its connecting wires within the sterilization load shall not exceed 3,2 mm^2.

NOTE This is to avoid significant influence on the sterilization process or the steam penetration by the temperature sensors.

8.2.4 The accuracy of the temperature sensor shall not be affected either by its connection wires, or by the environment in which it is placed, e.g. pressure, steam or vacuum.

8.2.5 The temperature sensors shall have a response time of $T_{0,9}$ < 1 s when tested in running water, with a flow rate greater than 0,2 m/s.

8.3 Thermometric recording instrument

8.3.1 A thermometric recording instrument(s) shall be used in conjunction with temperature sensors to record the temperatures measured in the locations specified in the tests described in this standard. It can also be used to check thermometric instruments fitted to the sterilizer.

8.3.2 If more than one instrument is used, means shall be provided to synchronise time within an accuracy of 1 s.

8.3.3 The thermometric recording instrument shall be able to record from at least three channels for the works and installation tests and from at least eight channels for the type test. The channels can be multiplexed or independent of each other. The sampling rate for each channel shall be at least once per 2,5 s.

8.3.4 The scale range for analogue thermometric recording instruments shall include 50 °C to 150 °C. The minor mark interval shall not exceed 1 K, shall have a minimum width of 1 mm and the chart speed shall be not less than 15 mm/min. The resolution shall be equal to or less than 0,5 K.

8.3.5 Thermometric recording instruments, producing digital records shall register and record in increments of not more than 0,1 K and the scale range shall include 50 °C to 150 °C.

8.3.6 The error of the temperature measuring system excluding temperature sensors shall not exceed ± 0,25 % of the scale range when tested in an ambient temperature of (20 ± 3) °C. The additional deviation due to a change in the ambient temperature shall not exceed 0,04 K/K.

8.3.7 The temperature recording instrument shall be calibrated. Calibration and documentation shall be in accordance with the manufacturer's instructions. The calibration shall include a temperature within the sterilization temperature band. Calibration shall be carried out using a working or reference standard, which is traceable to a national standard or a primary standard.

8.3.8 The temperature measurement system shall be verified with an independent temperature reference source at a temperature within the sterilization temperature band at the place of use and the deviation shall not exceed ± 0,35 K.

8.3.9 The temperature reference source shall meet the following requirements:

— it shall incorporate a reference standard thermometer which is traceable to a national standard or a primary standard and shall include the range 100 °C to 140 °C; the minor mark interval shall not exceed 0,2 K;

— it shall incorporate a pocket, sized to accommodate the temperature sensors as described in 8.2; the maximum temperature difference within the pocket shall not exceed 0,2 K and the control accuracy shall be to within ± 0,1 K over the range of 100 °C to 140 °C.

8.4 Pressure measurement and recording instrument

8.4.1 A pressure measurement and recording instrument shall be used in conjunction with a pressure sensitive measuring element to record the pressure within the sterilizer chamber during a test sterilization cycle. It can also be used to check the pressure measuring instrument(s) fitted to the sterilizer.

8.4.2 A pressure recording instrument shall record the pressure measured by a pressure sensitive element(s). The sampling rate for each channel shall be at least once per second. The instrument can be integrated into the temperature recording instrument as an additional channel calibrated for pressure.

8.4.3 The scale range for recording instruments producing analogue records shall include 0 kPa to 400 kPa (0 bar absolute to 4 bar absolute). The minor mark interval shall not exceed 4 kPa (0,04 bar), have a minimum width of 1 mm and the chart speed shall be not less than 15 mm/min. The resolution shall be at least 2 kPa (0,02 bar).

8.4.4 Pressure recording instruments producing digital records shall register and record in increments of not more than 1 kPa (0,01 bar) and the scale range shall include 0 kPa to 400 kPa (0 bar absolute to 4 bar absolute).

8.4.5 During application the error from 0 kPa to 400 kPa (0 bar absolute to 4 bar absolute) in the indicator and measuring/recording system shall not exceed ± 2 kPa when measured in an ambient temperature of (20 ± 3) °C.

8.4.6 The temperature coefficient of the measuring system shall not exceed 0,01 %/K at the temperature at which the pressure sensor is to be used.

8.4.7 The error due to a change in the environmental temperature shall not exceed 0,02 %/K.

8.4.8 The natural frequency of the pressure measuring instrument and connected tubing shall be not less than 10 Hz. The time constant (0 % to 63 %) for rising pressure shall not be greater than 0,04 s.

8.4.9 The pressure recording instrument shall be calibrated using a working or reference standard which is traceable to a national standard or a primary standard. Calibration and documentation shall be in accordance with the manufacturer's instructions. The calibration shall include the use of the minimum pressure which will occur in the air removal stage of any of the sterilization cycles –20 % and the maximum pressure that may occur in any of the sterilization cycles +10 %.

8.5 Test equipment for the performance of the air leakage test

8.5.1 Absolute pressure indicator

The absolute pressure indicator required for air leakage testing shall:

a) be either digital or analogue;

b) be graduated in kilopascals or millibars;

c) have a scale which includes 0 kPa to 16 kPa (0 mbar to 160 mbar);

d) have an absolute accuracy of ± 2 kPa or better over the scale range 4 kPa to 20 kPa (40 mbar to 200 mbar);

e) have an accuracy of linearity of 1 % or better over the scale range 4 kPa to 20 kPa (40 mbar to 200 mbar absolute);

f) for instruments with an analogue display be graduated in divisions not greater than 0,4 kPa (4 mbar) and with a scale displacement equal to or more than 1 mm/0,1 kPa (1 mm/mbar);

g) have a resolution of 0,1 kPa (1 mbar) for digital instruments.

8.5.2 Absolute pressure indicator for the determination of the ambient atmospheric pressure

The absolute pressure indicator required to determine the ambient atmospheric pressure shall:

a) be either digital or analogue;

b) be graduated in kilopascals;

c) have a scale which includes 80 kPa to 105 kPa (800 mbar to 1 050 mbar absolute);

d) have an accuracy of 1 % or better over the scale range 94 kPa to 105 kPa (940 mbar to 1 050 mbar absolute);

e) be graduated in divisions not greater than 0,4 kPa (4 mbar) and with the scale not greater than 0,1 kPa/mm (1 mbar/mm) for analogue instruments;

f) have a resolution of 0,1 kPa (1 mbar) for instruments with digital display.

NOTE The pressure measurement and recording instrument specified in 8.4 can be used.

8.5.3 Stopwatch

The stopwatch used in the air leakage test shall have an error of not more than ± 0,5 s over a period of 15 min.

8.6 Porous load

8.6.1 General

The porous load shall be:

a) composed of plain cotton sheets, bleached to a good white and having an approximate size of 450 mm × 300 mm. The number of threads per centimetre in the warp shall be (30 ± 6) and the number of threads per centimetre in the weft shall be (27 ± 5). The mass per unit area shall be approximately 180 g/m^2;

b) washed when new and when soiled;

c) not subjected to any fabric conditioning agent;

d) dried and aired;

e) stored for at least 1 h in an environment between 20 °C and 30 °C at a relative humidity of 40 % to 60 %.

NOTE 1 Test packs comprising different materials and of different sizes and weights can be used provided equivalence with the test pack specified above has been demonstrated.

NOTE 2 Fabric conditioning agents and or colouring dyes affect the characteristics of the fabric and contain volatiles which contribute to the content of non-condensable gases in the sterilizer chamber.

8.6.2 Small porous load, single wrapped

8.6.2.1 General

The small porous load is used to represent a small load of textiles which can be processed in a sterilizer and shall be composed of sheets of textile according to 8.6.1. The number of sheets shall be determined on the basis of volume and dimensions of the test pack. Unless 8.6.2.2 applies, the test pack shall fill (20 ± 5) % of the usable chamber space. The sheets shall be folded to form a parallelepiped as close to a cubic shape as the usable chamber space allows. In all cases the small porous load shall be wrapped in a single layer of packaging complying with the EN 868 series for this sterilization cycle type and used in the testing of the sterilizer.

8.6.2.2 Standard test pack according to EN 867-5

If the sterilizer usable chamber space has:

— a volume of more than 10 l and;

— diameter of at least 18 cm and;

— the sterilizer furniture does not hinder the positioning of the test pack;

the standard test pack according to EN 867-5 shall be used.

NOTE At the time of publication of this edition of EN 13060, revision of EN 867–5 is underway within CEN/TC 102 WG7 and ISO/TC 198 WG6. It is anticipated that changes will occur in the design and/or specification of the tests currently specified in EN 867–5. Users of this standard are advised to monitor the status of EN 867–5, which is expected to be replaced by prEN ISO 11140-6.

8.6.3 Small porous load, double wrapped

8.6.3.1 The small porous load is used to represent a small load of textiles which can be processed in a sterilizer and shall be composed of sheets of textile according to 8.6.1. The number of sheets shall be determined on the basis of volume and dimensions of the test pack. Unless 8.6.3.2 applies, the test pack shall fill (20 ± 5) % of the usable chamber space. The sheets shall be folded to form a parallelepiped as close to a cubic shape as the usable chamber space allows. In all cases the small porous load shall be wrapped in a double layer of packaging complying with the EN 868 series for this sterilization cycle type and used in the testing of the sterilizer.

8.6.3.2 If the sterilizer usable chamber space has:

— a volume of more than 10 l and;

— diameter of at least 18 cm and;

— the sterilizer furniture does not hinder the reception of the test pack;

the standard test pack according to EN 867-5 shall be used.

NOTE At the time of publication of this edition of EN 13060, revision of EN 867–5 is underway within CEN/TC 102 WG7 and ISO/TC 198 WG6. It is anticipated that changes will occur in the design and/or specification of the tests currently specified in EN 867–5. Users of this standard are advised to monitor the status of EN 867–5, which is expected to be replaced by prEN ISO 11140-6.

8.6.4 Small porous items, single wrapped

The test load of small porous items shall consist of multiple items with a total volume of less than 0,5 l or 5 % of the usable chamber space, whichever is smaller. The density of each individual item shall be equal to or less than 400 kg/m^3. The test load shall be composed of sheets of textile according to 8.6.1. The porous items shall be combined in a single pack with packaging complying with the EN 868 series, for this sterilization cycle type.

8.6.5 Small porous items, double wrapped

The test load of small porous items shall consist of multiple items with a total volume of less than 0,5 l or 5 % of the usable chamber space, whichever is smaller. The density of each individual item shall be equal to or less than 400 kg/m^3. The test load shall be composed of sheets of textile according to 8.6.1. The porous items shall be combined in a double pack with packaging complying with the EN 868 series, for this sterilization cycle type.

8.6.6 Full porous load, single wrapped

Use the test pack as defined in 8.6.2. The test pack shall be wrapped in a single layer of packaging complying with the EN 868 series for this sterilization cycle type. Fill the remaining usable chamber space with identical test packs or, when these will not fit, separate sheets of textile, to fill (90 ± 10) % of the usable chamber space.

8.6.7 Full porous load, double wrapped

Use the test pack as defined in 8.6.3. Fill the remaining usable chamber space with identical test packs or, when these will not fit, separate sheets of textile, to fill (90 ± 10) % of the usable chamber space.

8.7 Solid load, unwrapped

The solid load shall be composed of metal bolts. The metal bolts shall:

— be austenitic stainless steel, according to EN 10088-1;

— be hexagon head bolts ISO 4017 — M12 × 100;

— be cleaned, degreased and dried before use.

A number of bolts shall be used which represent as specified the maximum weight of unwrapped solid instruments which can be processed.

8.8 Solid load, single wrapped

The solid load shall be composed of metal bolts as defined in 8.7.

The total mass of the test load shall be the specified maximum load. The bolts shall be divided into groups and each group shall be wrapped in a single layer of packaging complying with the EN 868 series for this sterilization cycle type. The mass of each package shall be the specified maximum unit mass.

8.9 Solid load, double wrapped

The total mass of the test load shall be the specified maximum load. The bolts shall be divided into groups and each group shall be wrapped in a double layer of packaging complying with the EN 868 series for this sterilization cycle type. The mass of each package shall be the specified maximum unit mass.

8.10 Process challenge device (PCD) and chemical indicator for narrow lumen

This test device for narrow lumen shall comply with EN 867-5.

This process challenge device is used solely to demonstrate a basic minimum level of steam penetration. It is not intended to provide assurance that any particular medical device may be satisfactorily sterilized by the process. An example of a process challenge device for narrow hollow items is given in Annex G.

The chemical indicator to be used in the process challenge device shall comply with EN ISO 11140-1 and EN 867-5.

NOTE At the time of publication of this edition of EN 13060, revision of EN 867–5 is underway withinCEN/TC 102 /WG7 and ISO/TC 198/WG6. It is anticipated that changes will occur in the design and/or specification of the tests currently specified in EN 867–5. Users of this standard are advised to monitor the status of EN 867–5, which is expected to be replaced by prEN ISO 11140-6.

8.11 Process challenge device and chemical indicator for simple hollow item

This process challenge device is used solely to demonstrate a basic minimum level of steam penetration. It is not intended to provide assurance that any particular medical device may be satisfactorily sterilized by the process.

The simple hollow item shall be composed of four high density polytetrafluoroethylene (PTFE) rigid plastic cylindrical test tubes which shall be capable of holding thermocouples or chemical indicators and shall have the following dimensions:

a) Single ended open:

1) — internal diameter: 5 mm;

2) — external diameter: 9 mm;

3) — internal depth: 27,5 mm;

4) — external length: 33 mm;

5) — indicator dimensions: 27,5 mm × 6 mm × 0,7 mm.

b) Double ended open:

6) — internal diameter: 5 mm;

7) — external diameter: 9 mm;

8) — external length: 55 mm;

9) — indicator dimensions: 55 mm × 6 mm × 0,7 mm.

c) Single ended open:

10) — internal diameter: 10 mm;

11) — external diameter: 14 mm;

12) — internal depth: 55 mm;

13) — external length: 60 mm;

14) — indicator dimensions: 55 mm × 6 mm × 0,7 mm.

d) Double ended open:

15) — internal diameter: 10 mm;

16) — external diameter: 14 mm;

17) — external length: 110 mm;

18) — indicator dimensions: 110 mm × 6 mm × 0,7 mm.

The receptacles shall be packed individually and shall be wrapped in packaging complying with the EN 868 series for this sterilization cycle type.

The chemical indicators used in this test shall be printed on a non-absorbing indicator carrier and shall comply with EN ISO 11140-1 and EN 867-5.

NOTE 1 If necessary, the indicator can be slightly curved but not folded to allow fitting into the 5 mm inner diameter for a) and b).

NOTE 2 At the time of publication of this edition of EN 13060, revision of EN 867–5 is underway within CEN/TC 102 /WG7 and ISO/TC 198/WG6. It is anticipated that changes will occur in the design and/or specification of the tests currently specified in EN 867–5. Users of this standard are advised to monitor the status of EN 867–5, which is expected to be replaced by prEN ISO 11140-6.

8.12 Balance for load dryness test

The balance used for the load dryness test shall be capable of weighing the test load with an accuracy of 0,1 g or better.

9 Test programme

A recommended test programme to demonstrate conformity with the performance requirements is identified in Table 5. For the rationale of the different tests see Annex F.

Table 5 — Recommended test programme

Test	Sterilization cycle type		
	B	S	N
Air Leakage	T, W/I[b]	T[a], W/I[b]	T[a], W/I[b]
Dynamic chamber	T	T[c]	
Empty chamber	T, W/I	T, W/I	T, W/I
Solid load, unwrapped		T[f], W[f]	T, W
Solid load, single wrapped		T[d, f], W [d, f]	
Solid load, double wrapped	T	T[d], W[d]	
Narrow lumen	T, W	T[d], W[d]	
Simple hollow item		T[d, e], W[d, e]	
Small porous load, single wrapped		T[d, f], W[d, f]	
Small porous load, double wrapped	T	T[d], W[d]	
Full porous load, single wrapped		T[d, f, g], W[d, f, g]	
Full porous load, double wrapped	T	T[d], W[d]	
Small porous items, single wrapped		T[d, f], W[d, f]	
Small porous items, double wrapped		T[d], W[d]	
Dryness, solid load, unwrapped		T[d, f, g], W[d, f, g]	
Dryness, solid load, single wrapped		T[d, f], W[d, f]	
Dryness, solid load, double wrapped	T, W	T[d, f], W[d, f]	
Dryness, full porous load, single wrapped		T[d, f], W[d, f]	
Dryness, full porous load, double wrapped	T	T[d], W[d]	
Dryness, small porous items, single wrapped		T[d, f], W[d, f]	
Dryness, small porous items, double wrapped		T[d], W[d]	
Non-condensable gases		T [e]	T
Additional tests[h,i]		T[d], W[d]	
Dryness, small porous load, single wrapped		T[d, f, g], W[d, f, g]	
Dryness, small porous load, double wrapped		T[d, g], W[d, g]	
Microbiological tests[j]			

T: type test W: works test I: installation test
[a] If vacuum is used for air removal.
[b] If assembly on site is required.
[c] If the sterilization programme is designed for the sterilization of wrapped products.
[d] If claimed for this sterilization cycle type.
[e] Not if narrow lumen.
[f] Not if double wrapped is claimed.
[g] Not if dryness, solid load, double wrapped is claimed.
[h] Additional tests defined and performed as part of the type testing procedure shall comply with 7.1.
[i] The test using a dedicated PCD representing the most critical challenge as claimed for this sterilization cycle type.
[j] Optional microbiological tests for solid load, narrow lumen, simple hollow item, small porous load, full porous load and/or small porous items.

NOTE By planning and performing the test programme in a logical sequence, the risk for unnecessary repetitions of tests due to the need for technical alterations of the sterilizer in a late stage of the test sequence can be minimized.

If in addition to technical testing optional microbiologically tests are performed, the requirements in 5.6 shall apply. These tests do not replace any other tests specified in this European Standard.

10 Test methods

10.1 General requirements on technical tests

10.1.1 General

The results of the tests shall be interpreted with regard to the specified cycle variables of the temperature band for the cycle type, including the reproducibility of the pressure profile.

NOTE See 4.5, 4.6 and 5.3.

The test data shall be retained as part of the type/works/installation test documentation.

10.1.2 Apparatus

The equipment shall comply with Clause 8.

10.1.3 Type tests

For the thermometric measurements 8 temperature sensors shall be used. Any sensor connection cables shall be introduced into the sterilizer chamber through a test connection entry. The external pressure sensor shall be connected using a test connection. Type tests shall be repeated twice (three tests in all).

Unless it is specified that the sterilizer may only be used after a heat up cycle, at least one of the type tests shall be performed with the sterilizer starting up at ambient temperature and another test shall be performed immediately after a heat up cycle.

If applicable, an air leakage test shall be carried out as specified in 10.2.

One temperature sensor shall be placed in the free chamber space and another next to the control temperature sensor. All other temperature sensors shall be distributed throughout the chamber and the load, as specified in the particular test method.

10.1.4 Works and installation tests, as applicable

For the thermometric measurements 3 temperature sensors shall be used. Any sensor connection cables shall be introduced into the sterilizer chamber through a test connection entry. The external pressure sensor shall be connected using a test connection.

If applicable, an air leakage test shall be carried out as specified in 10.2.

10.2 Air leakage test

10.2.1 Apparatus

Equipment according to 8.5 or equivalent (see 10.2.2).

10.2.2 Type test and works/installation test procedure

Carry out the test with the sterilizer at ambient temperature. For the test result to be valid the chamber temperature change in the period t_2 to t_3 shall not exceed ± 3 K. If the sterilizer cannot be run without preheating, the test shall be carried out with a preheated sterilizer.

Connect the absolute pressure indicator to the sterilizer chamber with a means to protect it from the allowable working pressure of the sterilizing chamber if it is not designed to operate up to this pressure. Observe and record the ambient atmospheric pressure (p_0). Start the automated air leakage rate test cycle.

Observe and record the time (t_1) and the absolute pressure (p_1).

Wait for (300 ± 10) s after t_1 and then observe and record the absolute pressure in the chamber (p_2) and the time (t_2). The value of ($p_2 - p_1$) shall not exceed 0,1 ($p_0 - p_1$).

NOTE If the value of ($p_2 - p_1$) exceeds 0,1 ($p_0 - p_1$) this could be due to the initial presence of excessive moisture in the sterilizer chamber.

After a further (600 ± 10) s again observe and record the absolute pressure in the sterilizer (p_3) and the time (t_3).

At the end of the test calculate the rate of pressure rise (kPa/min) for the 600 s period using the Equation (2):

$$\frac{\Delta p}{\Delta t} = \frac{p_3 - p_2}{10} \qquad (2)$$

where

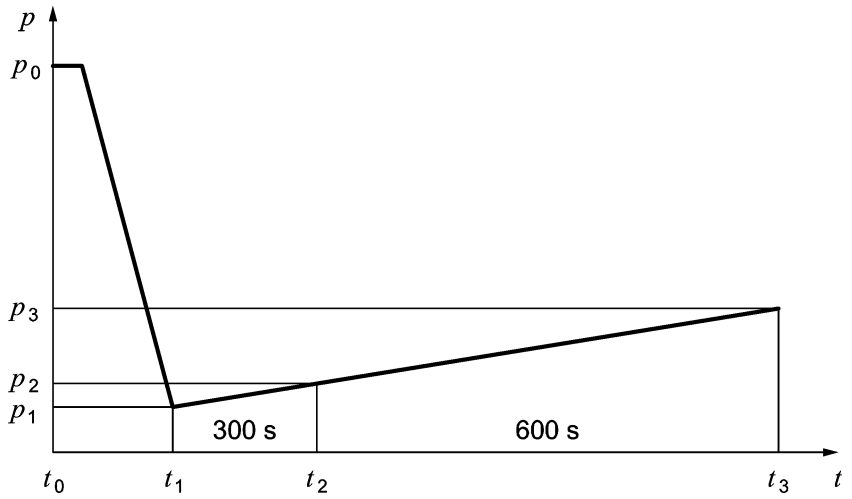
$\frac{\Delta p}{\Delta t}$ is the rate of pressure rise;

p_2 is the pressure after a period of 300 s;

p_3 is the pressure after a leakage time of 600 s.

Check for compliance with 5.2.

A different time interval may be used, provided that the accuracy and reproducibility is equal to or better than that obtained when using the equipment specified in 8.5. See Figure 2.



Key

p_0 ambient atmospheric pressure

p_1 lowest pressure level, which is equal to or lower than the level set for the cycle, during the air removal and steam penetration stage

p_2 pressure after a period of 300 s

p_3 pressure after a leakage time of 600 s

t_0 start of the test

t_1 time when the pressure level is reached

t_2 start of the leakage period

t_3 end of the test

Figure 2 — Example of a pressure curve during the air leakage test

10.3 Dynamic sterilizer chamber pressure test

10.3.1 Apparatus

Equipment according to 8.4.

10.3.2 Type test procedure

Attach the pressure recording instrument to the test connection. Select the sterilization cycle with the standard drying time and in addition, when the sterilizer has a number of such sterilization cycles, select the cycle which gives the largest pressure decrease per time unit. Carry out a sterilization cycle with the sterilizer chamber empty. The pressures throughout the sterilization cycle shall be recorded.

At the completion of the test, proceed as follows:

— examine the records specified above for compliance with the cycle specification;

— check the specified pressure switch points for compliance with the intended process as specified;

— check for compliance with 5.4.1.

10.4 Empty chamber test

10.4.1 Apparatus

Equipment according to 8.2, 8.3 and 8.4.

10.4.2 Type test procedure

Connect the test equipment as specified in 10.1. Place a temperature sensor in the active drain and one at the location of the control sensor and at least six in the usable chamber space at locations which are shown to include the highest and the lowest temperature and which will demonstrate the chamber temperature profile and so indicate the chamber temperature variance. Measure the temperature of the water, if the sterilizer is designed to retain water in the chamber after completion of the cycle, during at least one of the cycles.

Check for compliance with 5.3 and 5.4.2.

10.4.3 Works/installation test procedure

Connect the test equipment as specified in 10.1. Distribute the temperature sensors throughout the usable chamber space. Place the temperature sensors at the positions where the highest and lowest temperatures were indicated during the sterilization phase of the type test.

Check for compliance with 5.3 and 5.4.2.

10.5 Solid load test

10.5.1 Apparatus

Equipment according to 8.2, 8.3, 8.4 and either 8.7 (unwrapped) or 8.8 (single wrapped) or 8.9 (double wrapped).

10.5.2 Type and works/installation test procedures

Locate two temperature sensors at the positions where the highest and lowest temperatures were indicated during the empty chamber test. Fix the remaining temperature sensor in direct contact with a bolt using a single layer of autoclave tape with a width not exceeding 25 mm. This metal bolt shall be placed within the load. Place the load into the usable chamber space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle.

Check for compliance with 5.3.

NOTE Depending on the type of temperature sensors, problems can occur when the metal of the sensor is in direct contact with stainless steel, giving rise to electrochemical interference resulting from the direct contact of the sensor with the metal bolt.

10.6 Narrow lumen test

10.6.1 Apparatus

Equipment according to 8.10.

10.6.2 Type test and works/installation test procedure

Allow the process challenge device to reach ambient temperature and make sure that the internal parts are dry before using it.

Carry out a sterilization cycle with the sterilizer chamber empty. Place the chemical indicator into the indicator holding device. Close and seal the capsule. Check that the plateau period does not exceed the endpoint of the chemical indicator (if necessary reduce the plateau period). Place the process challenge device into the usable chamber space according to the user instructions provided with the sterilizer, using the sterilizer furniture. The sterilizer chamber shall be empty except for the sterilizer furniture. Immediately start the sterilization cycle. At the end of the sterilization cycle remove the process challenge device from the chamber. Remove the chemical indicator from the indicator holding device.

Check for compliance with 5.3.3.

10.7 Simple hollow item test

10.7.1 Thermometric test (optional for works and installation tests)

10.7.1.1 Apparatus

Equipment according to 8.11.

10.7.1.2 Type test procedure

Allow the receptacles to reach ambient temperature before using them and make sure that the internal parts are dry.

Connect the equipment as specified in 10.1. Distribute at least 6 temperature sensors throughout the usable chamber space. Locate four of these temperature sensors inside the receptacles and ensure that each receptacle includes one temperature sensor. For single ended open receptacles locate the temperature sensor at the bottom of the receptacle. For double ended open receptacles locate the temperature sensor in the middle of the receptacle. Ensure that there is no contact between the temperature sensitive part of the sensors and the receptacle. Turn the wires of the temperature sensors back at the inlet of the test receptacle and fix them by a piece of autoclave tape at the outside of the receptacle. Locate the two remaining temperature sensors at positions where the highest and lowest temperature were indicated during the empty chamber test. Place the load into the usable chamber space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle.

Check for compliance with 5.3.1.

10.7.1.3 Works/installation test procedure

Allow the receptacles to reach ambient temperature before using them and make sure that the internal parts are dry.

Connect the equipment as specified in 10.1. Distribute the temperature sensors throughout the usable chamber space. Place one of these temperature sensors in the test receptacle shown to be the most critical during the type test. Locate another temperature sensor at the position shown to be the most critical during the empty chamber test. Place the load into the usable chamber space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle.

Check for compliance with 5.3.1.

10.7.2 Chemical indicator system test (works or installation tests only)

10.7.2.1 Apparatus

Equipment according to 8.11.

10.7.2.2 Works/installation test procedure

Allow the receptacles to reach ambient temperature before using them and make sure that the internal parts are dry.

Fit each test receptacle with a chemical indicator. Check that the holding time does not exceed the response time of the chemical indicator. If necessary reduce the holding time to be the endpoint of the chemical indicator. Place the load into the usable chamber space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle. Remove the test receptacles from sterilization chamber at the end of the sterilization cycle. Remove the chemical indicator from the test receptacle and check the colour with the specifications for the indicator.

Check for compliance with 5.3.3.

10.8 Small porous load test

10.8.1 Apparatus

Equipment according to 8.2, 8.3, 8.4 and 8.6.2 (single wrapped) or 8.6.3 (double wrapped).

10.8.2 Type test procedure

Connect the equipment specified in 10.1. Distribute at least six temperature sensors throughout the usable chamber space. Place at least four of these temperature sensors in the test load as specified in Figure 3. Close and seal the packaging and ensure a full closure throughout the sterilization cycle. Locate the two remaining temperature sensors at the positions where the highest and lowest temperature were indicated during the empty chamber test. Place the load into the usable chamber space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle.

Check for compliance with 5.3.

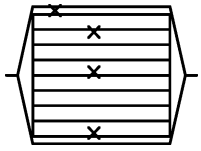


Figure 3 — Location of temperature sensors in the small porous load type test

10.8.3 Works/installation test procedure

Connect the equipment specified in 10.1. Distribute the temperature sensors throughout the usable chamber space. Place one of these temperature sensors in the test load as indicated in Figure 4. Locate the remaining temperature sensors at the positions with the highest and lowest temperature as identified during the empty chamber test. Close and seal the packaging and ensure a full closure throughout the sterilization cycle. Place the load into the usable chamber space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle.

Check for compliance with 5.3.

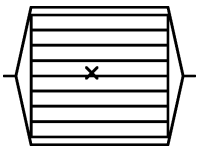


Figure 4 — Location of temperature sensors in the small porous load works/installation test

10.9 Full porous load test (single and double wrapped)

10.9.1 Apparatus

Equipment according to 8.2, 8.3, 8.4 and 8.6.6 (single wrapped) or 8.6.7 (double wrapped).

10.9.2 Type test procedure

Connect the equipment as specified in 10.1. Distribute at least six temperature sensors throughout the usable chamber space. Place at least four of these temperature sensors in the test load as indicated in Figure 5. Close and seal the packaging and ensure a full closure throughout the sterilization cycle. Locate the two remaining temperature sensors at the positions where the highest and lowest temperature were indicated during the empty chamber test. Place the load into the usable chamber space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle.

Check for compliance with 5.3.

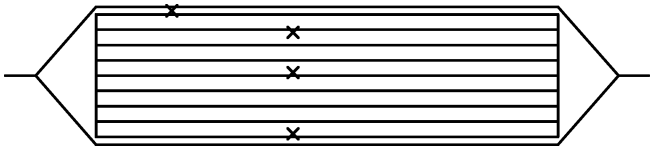


Figure 5 — Location of temperature sensors in the full porous load type test

10.9.3 Works/installation test procedure

Connect the equipment as specified in 10.1. Distribute the temperature sensors throughout the usable chamber space. Place one of these temperature sensors in the test load as indicated in Figure 6. Close and seal the packaging and ensure a full closure throughout the sterilization cycle. Locate the remaining temperature sensor(s) at the positions with the highest and lowest temperature as identified during the empty chamber test. Place the load into the usable chamber space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle.

Check for compliance with 5.3.

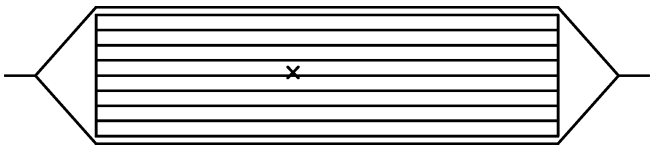


Figure 6 — Location of temperature sensors in the full porous load works/installation test

10.10 Small porous items test (single and double wrapped)

10.10.1 Apparatus

Equipment according to 8.2, 8.3, 8.4 and 8.6.4 (single wrapped) or 8.6.5 (double wrapped).

10.10.2 Type test procedure

Connect the equipment as specified in 10.1. Pre-heat the sterilizer by carrying out a sterilization cycle with the sterilizer chamber empty. Distribute at least six temperature sensors throughout the usable chamber space. Place at least four of these temperature sensors in the test load as indicated in Figure 7. Close and seal the packaging by a method that will ensure the package remains sealed throughout the sterilization cycle. Locate the two remaining temperature sensors at the positions where the highest and lowest temperature were indicated during the empty chamber test. Place the load into the usable chamber space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle.

Check for compliance with 5.3.

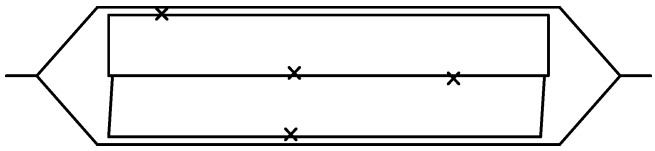


Figure 7 — Location of temperature sensors in the test load 'small porous items' type test

10.10.3 Works/installation test procedure

Connect the equipment as specified in 10.1. Distribute the temperature sensors throughout the usable chamber space. Locate one temperature sensor in the test load as indicated in Figure 8. Locate the remaining temperature sensor(s) in the positions shown to be most critical during the empty chamber test. Close and seal the packaging by a method that will ensure the package remains sealed throughout the sterilization cycle. Place the load into the usable chamber space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle.

Check for compliance with 5.3.

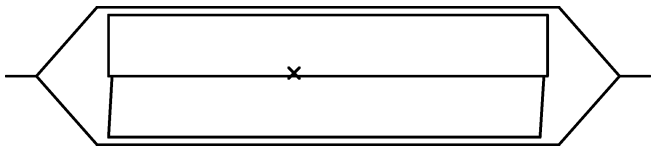


Figure 8 — Location of temperature sensors in the test load 'small porous items' works/installation test

10.11 Solid load dryness test

10.11.1 Apparatus

Equipment according to 8.5.3 and 8.12 with either 8.7 (unwrapped) or 8.8 (single wrapped) or 8.9 (double wrapped).

10.11.2 Type test procedure

Select the sterilization cycle to be tested. Weigh the test load including its packaging (if used, trays may be included), and record its mass (m_1).

Place the test load in the usable chamber space supported by the chamber furniture in a position such that it will acquire the maximum moisture. Immediately start the sterilization cycle. Upon completion of the sterilization cycle remove the test load from the sterilizer chamber. Weigh the test load within 2 min after the "cycle complete" indication. Record the mass (m_2).

Calculate the change in moisture content (C) using Equation (3):

$$C = \frac{m_2 - m_1}{m_1} \times 100 \quad (3)$$

where

C is the change in moisture content, in per cent;

m_1 is the mass of the test load before sterilization, in grams;

m_2 is the mass of the test load after sterilization, in grams.

Check for compliance with 5.5.

10.11.3 Works/installation test procedure

Select the cycle to be tested and, if required, carry out a sterilization cycle with the sterilizer chamber empty. Place the test load in the usable chamber space supported by the chamber furniture in a position such that it will acquire the maximum moisture. Immediately start the sterilization cycle. Upon completion of the sterilization cycle remove the test load from the sterilizer chamber and visually inspect. In case of doubt, perform the test as specified for the type test.

Check for compliance with 5.5.

10.12 Porous load dryness test (small and full, single and double wrapped)

10.12.1 Apparatus

Equipment according to 8.5.3, 8.12 and either 8.6.2 (small load single wrapped), 8.6.3 (small load double wrapped), 8.6.6 (full load single wrapped) or 8.6.7 (full load double wrapped).

10.12.2 Type test procedure

Select the sterilization cycle to be tested and carry out a sterilization cycle with the sterilizer chamber empty. Weigh the test load and record its mass (m_1). Place the test load in the usable chamber space supported by the chamber furniture in a position such that it will acquire the maximum moisture. Immediately start the sterilization cycle. Upon completion of the sterilization cycle remove the test load from the sterilizer chamber. Check the test load by visual inspection. No moisture spots shall be visible on the test load or the wrapping material. Weigh the test load within 2 min after the "cycle complete" indication. Record the mass (m_2). Calculate the change in moisture content using Equation (3).

Check for compliance with 5.5.

10.12.3 Works/installation test procedure

Select the cycle to be tested and carry out a sterilization cycle with the sterilizer chamber empty. Place the test load in the usable chamber space supported by the chamber furniture in a position which will cause the maximum moisture. Immediately start the sterilization cycle. Upon completion of the sterilization cycle remove the test load from the sterilizer chamber. Check the test load by visual inspection. No moisture spots shall be visible on the test load or the wrapping material. In case of doubt, perform the test as specified for the type test.

Check for compliance with 5.5.

10.13 Small porous items dryness test (single and double wrapped)

10.13.1 Apparatus

Equipment according to 8.5.3, 8.12 and either 8.6.4 (single wrapped) or 8.6.5 (double wrapped).

10.13.2 Type test procedure

Carry out the test as specified in 10.12.2 for the porous load dryness test but using the test load for small porous items (8.6.4 or 8.6.5).

Check for compliance with 5.5.

10.13.3 Works/installation test procedure

Carry out the test as specified in 10.12.3 for the porous load dryness test but using the test load for small porous items (8.6.4 or 8.6.5).

Check for compliance with 5.5.

10.14 Non-condensable gases test

10.14.1 Apparatus

Equipment consisting of:

a) 50 ml burette;

b) 250 ml measuring cylinder;

c) water condenser consisting of a tank capable of holding sufficient water to condense the steam from the sterilizer chamber without exceeding 75 °C at the end of the test, and with an overflow outlet which allows the excess water to be collected in the 250 ml measuring cylinder;

d) a suitable bulkhead type fitting which can be accommodated by a suitable entry point either in the sterilizer door or chamber with the nozzle end of the fitting located inside the sterilizer chamber. The fitting should have a bore no greater than 1 mm in diameter and be designed with a short nozzle which is capable of accommodating a short length of narrow bore rubber tubing. See Figure 9;

e) a control valve which can be fitted/connected to the bulkhead type fitting above, to both isolate the chamber from the external atmosphere and control the steam flow during the test.

10.14.2 Type test

Assemble the apparatus as illustrated in Figure 10. Fill the water condenser with sufficient cold water to prime the overflow pipe. Using a short length of small diameter silicon tube, fit a large syringe (25 ml or 50 ml) to the nozzle of the bulkhead fitting.

With the control valve open, prime the control valve, connecting tubing and the fitting with water by drawing air out of the capillary tube using the syringe. In order to remove as much air from the system as possible, continue to draw on the syringe as water is seen to issue from the capillary tube. Hold the syringe with the connection upper most, pull and push the syringe to help release any air bubble in the supply rubber tube or capillary tube.

Continue draw water into the syringe until no air bubbles are seen in the water issuing from the capillary tube. Shut off the control valve and remove the tubing and syringe from the fitting nozzle.

Top up the condenser with water. Using a short length of rubber tubing, connect the syringe to the burette tap and open the burette valve. Using the syringe, draw water into the burette until the water level reaches the zero mark on the burette. Close off the burette valve and remove the syringe and tubing. Top up the condenser with water until water flows from the overflow pipe. Wait for water to stop flowing from the overflow pipe and then place the 250 ml measuring cylinder under the condenser overflow pipe.

Record the temperature of the water in the condenser, close the sterilizer door and operate the cycle under test. Observe the sterilizer display and when the start of the holding period is reached record the chamber temperature and pressure. Then switch off the sterilizer electric supply.

Slowly open the control valve to allow the atmosphere in the sterilizer chamber to flow into the condenser water. Regulate the steam flow such that all of the steam condenses within the water.

Continue to condense the chamber contents until the steam flow slows. At this point the control valve can be carefully opened fully to allow the final flow of steam to be condensed.

When the flow of steam from the sterilizer has stopped, turn off the control valve.

Record the volume of gas collected in the burette (V_b), the water temperature in the condenser and the volume of water collected in the measurement cylinder (V_c).

Calculate the ratio of the volume of non-condensable gases to the volume of condensed water collected and express as a percentage, using Equation (4):

$$N = \frac{V_b}{V_c - V_b} \times 100 \quad (4)$$

where

N is the ratio of the volume of non-condensable gases to the volume of condensed water, in per cent;

V_b is the volume of non-condensable gases, in millilitres;

V_c is the total volume of condensed water collected, in millilitres.

Repeat this test at the start, middle and end of plateau period. Check for compliance with 5.7.

Dimensions in millimetres

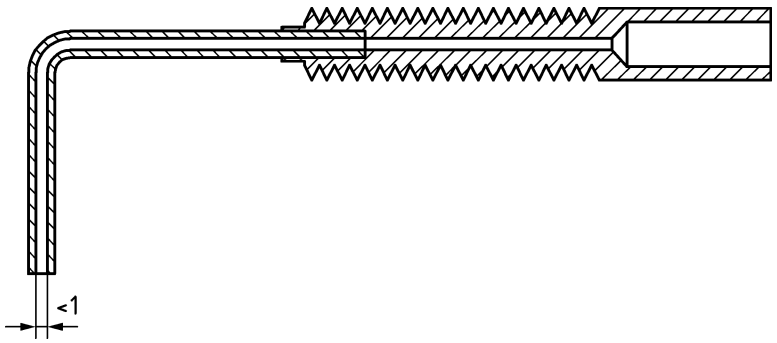
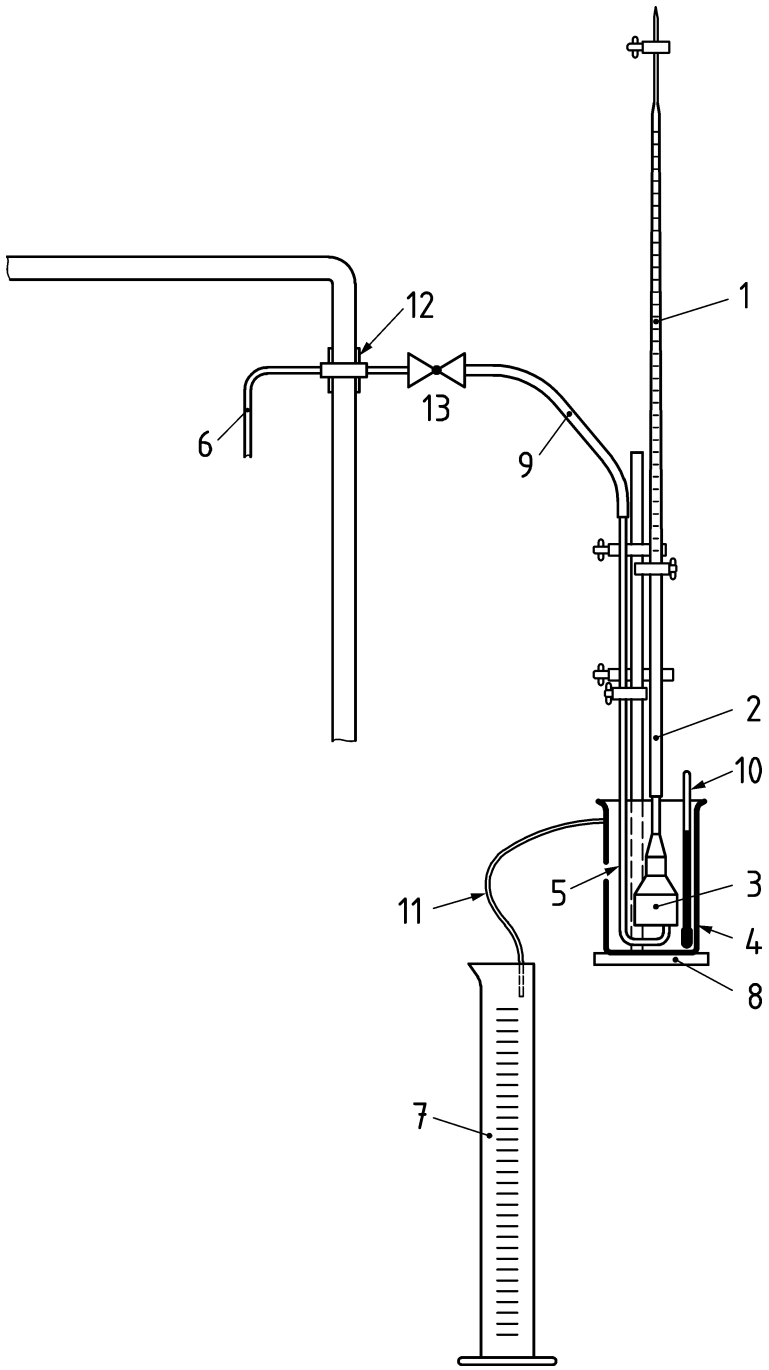


Figure 9— Bulkhead fitting



Key

1	50 ml burette	6	capillary sampling tube	11	overflow pipe
2	rubber tubing	7	250 ml measuring cylinder	12	coupling
3	funnel with parallel sides	8	burette stand	13	control valve
4	2 000 ml container	9	rubber tubing		
5	steam sampling pipe	10	temperature measurement system		

NOTE The exact position of the capillary tube inlet inside the sterilizer chamber is not specified as in practice, the collected gas volume has been found to vary depending on the capillary tube position in some sterilizers.

Figure 10 — Diagrammatic representation of the apparatus for the measurement of non-condensable gases

10.15 Microbiological test for solid loads

10.15.1 Apparatus

Equipment according to 8.7 (unwrapped) or 8.8 (single wrapped) or 8.9 (double wrapped).

At least five biological indicators complying with EN ISO 11138-3. An additional biological indicator is not processed and serves as a reference indicator positive control.

10.15.2 Type test and works/installation test procedure

Secure four biological indicators at the locations used for the temperature sensors in the load during the test according to 10.5. Close and seal the packaging by a method that will ensure it remains sealed throughout the sterilization cycle. Check that the plateau period does not exceed the F_{bio} value (see EN ISO 17665-1:2006, D.4.2) of the biological indicator. If necessary, adjust the plateau period. Place the load into the usable chamber space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle. After sterilization incubate the sterilized and the non-sterilized indicator according to EN ISO 11138-3.

After the incubation time, check for compliance with 5.6.

10.16 Microbiological test for narrow lumens

10.16.1 Apparatus

Equipment according to 8.10. Instead of the chemical indicator an inoculated carrier complying with EN ISO 11138-3 shall be used. The dimensions of the inoculated carrier shall be 36 mm × 6 mm × 0,7 mm. An identical inoculated carrier shall be used for the reference biological indicator and remains unprocessed.

10.16.2 Type test and works/installation test procedure

Carry out a sterilization cycle with the sterilizer chamber empty. Place the inoculated carrier into the indicator holding device. Close and seal the device. Wrap the device in a sheet of textile. Check that the plateau period time does not exceed the specified response time of the biological indicator. If necessary, adjust the plateau period. Place the process challenge device into the usable chamber space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle. At the end of the sterilization cycle remove the process challenge device from the chamber. Remove the inoculated carrier from the indicator holding device. Incubate the sterilized inoculated carrier and the non-sterilized indicator according to EN ISO 11138-3.

After the incubation time, check for compliance with 5.6.

Allow the process challenge device to cool to ambient temperature and make sure that the internal parts are dry before using it again.

10.17 Microbiological test for simple hollow item

10.17.1 Apparatus

Equipment according to 8.11. Instead of the chemical indicator system an inoculated carrier complying with EN ISO 11138-3 shall be used. The dimensions of the inoculated carrier shall be 36 mm × 6 mm × 0,7 mm. An identical inoculated carrier shall be used as the reference biological indicator and remain unprocessed.

10.17.2 Type test and works/installation test procedure

Fit each test tube with a biological indicator. Position the inoculated carrier in the single ended open receptacles at the bottom of the tube. Locate the inoculated carrier in the double ended open receptacles in the middle of the tube. Check that the plateau period does not exceed the F_{bio} value (see EN ISO 17665-1:2006, D.4.2) of the inoculated carrier. If necessary, adjust the plateau period. Place the load into the usable chamber space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle. Remove the test tubes from the sterilization chamber at the end of the sterilization cycle. Remove the inoculated carriers from the test tubes. Incubate the sterilized inoculated carriers and the non-sterilized reference indicator according to EN ISO 11138-3.

After the incubation time, check for compliance with 5.6.

Allow the receptacles to cool to ambient temperature before using them again and make sure that the internal parts are dry.

10.18 Microbiological test for small porous loads

10.18.1 Apparatus

Equipment according to 8.6.2 (single wrapped) or 8.6.3 (double wrapped).

At least five biological indicators complying with EN ISO 11138-3.

10.18.2 Type test and works/installation test procedure

Secure four biological indicators at the locations used for the temperature sensors in the load during the test according to 10.8. A fifth biological indicator is not processed and serves as a reference indicator positive control. Close and seal the packaging by a method that will ensure it remains sealed throughout the sterilization cycle. Check that the plateau period does not exceed the specified exposure of the biological indicator. If necessary, adjust the plateau period time. Place the load into the usable chamber space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle. After sterilization, incubate the sterilized indicators and the non-sterilized biological indicator according to EN ISO 11138-3. After the incubation time, check for compliance with 5.6.

10.19 Microbiological test for full porous loads

10.19.1 Apparatus

Equipment according to 8.6.6 (single wrapped) or 8.6.7 (double wrapped).

At least five biological indicators complying with EN ISO 11138-3.

10.19.2 Type test and works/installation test procedure

Secure four biological indicators at the locations used for the temperature sensors in the load during the test according to 10.9. A fifth biological indicator is not processed and serves as a reference indicator positive control. Close and seal the packaging by a method that will ensure it remains sealed throughout the sterilization cycle. Check that the plateau period does not exceed the specified exposure time of the biological indicator. If necessary, adjust the plateau period. Place the load into the usable chamber space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle. After sterilization incubate the sterilized indicators and the non-sterilized biological indicator according to EN ISO 11138-3.

After the incubation time, check for compliance with 5.6.

10.20 Microbiological test for small porous items

10.20.1 Apparatus

Equipment according to 8.6.4 (single wrapped) or 8.6.5 (double wrapped).

At least five biological indicators complying with EN ISO 11138-3.

10.20.2 Type test and works/installation test procedure

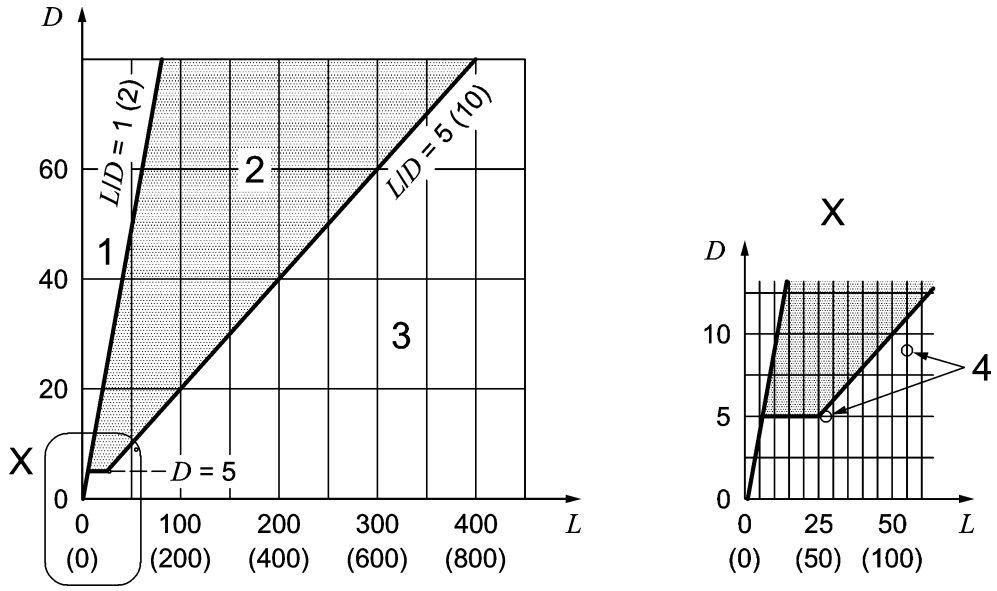
Secure four biological indicators at the locations used for the temperature sensors in the load during the test according to 10.10. A fifth biological indicator is not processed and serves as a reference indicator positive control. Close and seal the packaging by a method that will ensure it remains sealed throughout the sterilization cycle. Check that the plateau period does not exceed the specified response time of the biological indicator. If necessary, adjust the plateau period. Place the load into the usable chamber space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle. After sterilization incubate the sterilized indicators and the non-sterilized indicator according to EN ISO 11138-3.

After the incubation time, check for compliance with 5.6.

Annex A
(informative)

Clarification of the definition of narrow lumens and simple hollow items (see 3.18 and 3.30)

Dimensions in millimetres



Key

1 non-hollow (solid) area

2 simple hollow items

3 narrow lumen area

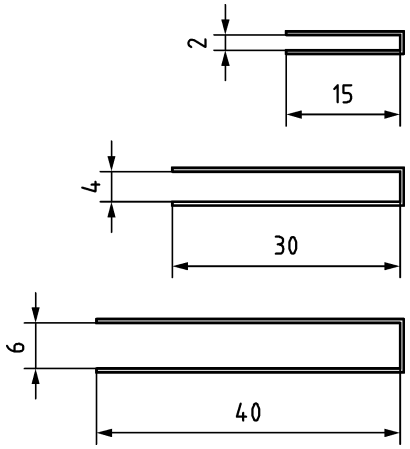
4 simple hollow item process challenge devices (PCD) according to 8.11

NOTE 1 The ratio of the length of cavity to diameter is less than 1.

NOTE 2 Numbers in parentheses are given for double ended open spaces. The ranges for diameter *D* and length *L* are limited by the chamber dimensions.

Figure A.1 — Graphical representation of the definition of narrow lumens and simple hollow items

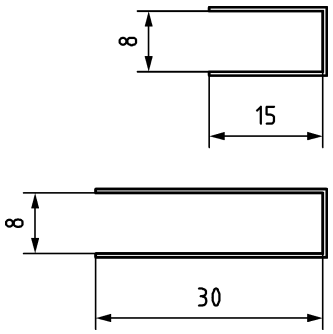
Dimensions in millimetres



NOTE The ratio of the length of cavity to diameter is greater than 5 for all objects.

Figure A.2 — Narrow lumens

Dimensions in millimetres



NOTE The ratio of the length of cavity to diameter is greater than 1 and less than 5 for both objects.

Figure A.3 — Simple Hollow Items

Annex B
(informative)

Process evaluation system

Usually a steam sterilization process is evaluated by interpreting the record of the physical parameters pressure, temperature and time. A trained operator is able to assess the sterilization process and to decide whether or not the loads are sterilized and ready for use. Operators of small steam sterilizers are not always able to interpret the sterilization process with the records of the physical parameters.

The application of a recorder on a small sterilizer should be considered if due interpretation by the operator can be expected or if a hard copy is required. As an alternative to a chart recorder, a process evaluation system can be considered. This system monitors the various factors essential to ensure sterilization and indicates to the operator if the cycle is acceptable or not.

Basically a process evaluation system should answer the same questions as the operator judging the records.

— Was the pressure(s) in the first vacuum and in all the pulses that followed low enough?

— Was the time taken to reach this pressure(s) within the limits?

— Was the pressure(s) in the first steam pulse and in all the pulses that followed high enough?

— Was the time taken to reach this pressure(s) within the limits?

— Was the pressure(s) during the holding time within the limits?

— Was the time taken to reach this pressure(s) within the limits?

— Was the temperature during the holding time within the limits?

— Were the temperatures, including the theoretical temperature, during the holding time within the limits?

— Was the holding time long enough?

— Was the drying pressure(s) low enough?

— Was the drying time long enough?

These questions should be answered with respect to the information given according to 4.5.3.1 and 4.8.1.

Should any of these questions be answered with “no”, the sterilization should be considered not satisfactory and a "sterilization process fault" should be indicated. The load should be considered non-sterile.

Annex C
(informative)

Suggested maximum limits of contaminants in and specification for water for steam sterilization

Table C.1 — Contaminants of condensate and feed water

	Feed water	Condensate
Evaporate residue	≤ 10 mg/l	≤ 1,0 mg/l
Silicium oxide, SiO_2	≤ 1 mg/l	≤ 0,1 mg/l
Iron	≤ 0,2 mg/l	≤ 0,1 mg/l
Cadmium	≤ 0,005 mg/l	≤ 0,005 mg/l
Lead	≤ 0,05 mg/l	≤ 0,05 mg/l
Rest of heavy metals, excluding iron, cadmium, lead	≤ 0,1 mg/l	≤ 0,1 mg/l
Chloride	≤ 2 mg/l	≤ 0,1 mg/l
Phosphate	≤ 0,5 mg/l	≤ 0,1 mg/l
Conductivity (at 20 °C)	≤ 15 μS/cm	≤ 3 μS/cm
pH value	5 to 7,5	5 to 7
Appearance	colourless, clean, without sediment	colourless, clean, without sediment
Hardness	≤ 0,02 mmol/l	≤ 0,02 mmol/l
NOTE The condensate is produced from steam that has been taken from the empty sterilizer chamber.		

Compliance should be tested in accordance with acknowledged analytical methods. The use of water for steam generation with contaminants at levels exceeding those given in this Table can greatly shorten the working life of a sterilizer.

Annex D
(informative)

Example of a table to be supplied with pre-purchase documentation and with the instructions for use

The example covers a small sterilizer complying with this European Standard which provides five different cycles:

a) one for full porous loads and identified as a type B cycle,

b) one for unwrapped solid instruments and identified as a type N cycle, and

c) three cycles identified as type S cycles,

1) one for hollow instruments providing a level of drying but not sufficient for drying porous materials or wrappings,

2) one for small porous items with a drying cycle capable of drying wrappings, and

3) one for specific medical devices which have been validated individually with the validation information being included in the documentation.

Table D.1 — Example

Type tests	Sterilization cycle type				
	B	N	S1	S2	S3
Dynamic sterilizer chamber pressure	X	X	X	X	X
Air Leakage	X		X	X	X
Empty chamber	X	X	X	X	X
Solid load	X	X	X	X	X
Small porous items	X				
Small porous loads	X				
Full porous load	X				
Simple hollow item	X		X		
Narrow lumen	X		X		
Multiple wrapping	X				
Dryness, solid load	X	X	X	X	
Dryness, porous load	X			X	
Non-condensable gases		X			
Specific medical devices (see manual)					X
X: in compliance with all applicable clauses of this European Standard.					

Annex E
(informative)

Load support systems

E.1 Sterilizers that have a horizontal chamber should be provided with load trays. The base of each tray and, if fitted, each lid should be perforated. Each tray should be self-supporting when withdrawn to one-half its length from the chamber.

E.2 Sterilizers that have a vertical chamber should be provided with load baskets. At least the horizontal surfaces of each basket should be perforated.

E.3 Each load tray and/or basket should be fully removable, self-draining and provided with means to keep its under-surface not less than 5 mm from a plane horizontal supporting surface.

E.4 The area of the perforations on each load tray and/or basket should be not less than 10 % of area of the perforated surfaces. The perforations should be uniformly distributed and should each have an area of not less than 20 mm^2.

E.5 The trays and/or baskets and the perforations should be so designed that, when placed in the sterilizer, they do not obstruct the drainage of the condensate from, or the penetration of steam into the trays and/or baskets.

Annex F
(informative)

Rationale for the tests

F.1 Air leakage test

The air leakage test is used to demonstrate that the quantity of air leakage into the sterilizer chamber during the periods of vacuum does not exceed a level which will inhibit the penetration of steam into the sterilization load and will not be a potential cause of re-contamination of the sterilization load during drying.

F.2 Dynamic sterilizer chamber pressure test

The dynamic sterilizer chamber pressure test is used to demonstrate that the rate of pressure change occurring in the sterilizer chamber during a sterilization cycle does not exceed a level which could cause damage to the packaging materials. This level is used as a performance requirement for materials complying with EN 868 series and has been chosen on the basis of a compromise between the needs of cost effective packaging and short, efficacious sterilization cycles.

F.3 Empty chamber test

The empty chamber test is performed to evaluate the sterilizer performance without the influence of a load. It allows the actual temperature and pressure settings to be verified against the intended settings.

F.4 Small porous load test

The small porous load test is used to demonstrate that, at the levels at which the controls are set, that steam will penetrate rapidly and evenly into the specified test pack.

F.5 Full porous load test

The full porous load test is used to demonstrate that, at the levels at which the controls are set, the required sterilizing conditions will be obtained in the maximum density of porous load material which a sterilizer conforming to this European Standard is designed to process.

F.6 Solid load test

The solid load test is used to demonstrate that, at the levels at which the controls are set, the required sterilizing conditions will be obtained throughout the load. The load shall comprise the maximum mass of solid instruments which a sterilizer conforming to this European Standard is designed to process.

F.7 Small porous items

The small porous items test is used to demonstrate that, at the levels at which the controls are set, the required sterilizing conditions will be obtained in small porous items which a sterilizer conforming to this European Standard is designed to process.

F.8 Narrow lumen test

The process challenge device for hollow loads according to EN 867-5 represents a defined challenge for air removal and steam penetration of specific lumen geometry classified to be narrow lumen (see 3.18). This PCD is intended to represent a minimum level for air removal and steam penetration performance of a sterilizer performing a sterilization cycle of type B or type S (as applicable) according to this European Standard. However, medical devices containing a narrow lumen can require a higher level of air removal and steam penetration performance than that required by the EN 867-5 PCD for hollow loads.

F.9 Simple hollow item test

The simple hollow item test is used to demonstrate that, at the levels at which the controls are set, the required sterilizing conditions will be obtained in a process challenge device which conforms to the specification for simple hollow item which a sterilization cycle conforming to this European Standard is designed to process.

F.10 Solid load dryness test

The solid load dryness test is performed with a reference sterilization load and is used to demonstrate that the sterilization cycle is unlikely to cause moisture problems in routine production loads.

F.11 Porous load dryness test

The porous load dryness test is used to demonstrate that the sterilization cycle without additional drying will not cause an increase in moisture in a porous load sufficient to inhibit the barrier properties of the packaging.

F.12 Non-condensable gases test

The non-condensable gases test is used to determine the amount of non-condensable gases in the chamber.

F.13 Microbiological test for small porous loads

The microbiological test for small porous loads is intended to show that when the controls are set at the levels at which compliance with the requirements for the small porous load has been demonstrated in the technical test, recovery of test organisms from the biological indicator placed in the test load cannot be achieved after the completion of a sterilization cycle.

F.14 Microbiological test for full porous loads

The microbiological test for full porous loads is intended to show that, when the controls are set at the levels at which compliance with the requirements for the full porous load has been demonstrated in the technical test,

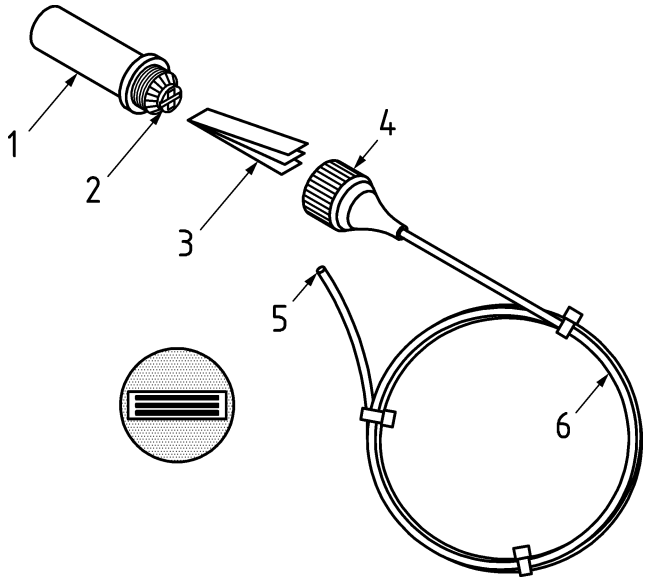
recovery of test organisms from the biological indicator placed in the test load cannot be achieved after the completion of a sterilization cycle.

F.15 Microbiological test for small porous items

The microbiological test for small porous items is intended to show that, when the controls are set at the levels at which compliance with the requirements for the small porous items has been demonstrated in the technical test, recovery of test organisms from the biological indicator placed in the test load cannot be achieved after the completion of a sterilization cycle.

Annex G
(informative)

Example of a process challenge device for narrow lumen



Key

1 capsule
2 sealing
3 indicator
4 connector
5 open end
6 tube

Figure G.1 — Example of a process challenge device for narrow lumen

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42 EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this European Standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this European Standard given in Table ZA.1 confers, within the limits of the scope of this European Standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clauses/sub-clauses of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.8.4, Table 4 (27, 33)	7.2	Reference is made to EN 61010–2-40:2005, 5.4.4, 5.4.5
4.2, 6.3, 4.7, Annex C	7.3, 1st part	Reference is made to EN 61010–2-040:2005, 5.4.3 o) and EN 61010–1: 2010, 11.1, 11.2
	7.3, 2nd part	Equipment is not intended to administer medicinal products.
	7.4	Sterilizer is not likely to incorporate medicinal products
4.2, 4.7, 6.1, 6.3	7.5, 1st paragraph	Leaking is also addressed by references to EN 61010–2-040:2005, 11.3; 11.4, 11.7, 11.101
	7.5, 2nd and 3rd paragraph	These requirements are not likely to apply for steam sterilizers,
4.3.3, 4.3.4, 4.4.3.5, 4.5.3, 5.2, 5.7, 6.3	7.6	Air leakage into the chamber may compromise the process.
4.3.1, 4.3.3, 4.7, Table 5 (10, 12, 30, 36, 37); 4.10, 6.1, Annex E	9.1	Reference is also made to EN 61010–2-040:2005, 5.4.3 and Clause 14
4.3.1, 6.1, 6.3, 4.1, 6.4, 4.3.2, 4.7.1, Table 5 (12, 24), 6.2	9.2, 1st and 2nd dash	Reference is also made to EN 61010–2-040:2005, 1.4, 7.5.101 and 7.101; further to EN 13445 (series), and

Clauses/sub-clauses of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
		EN 61326–1:2013.
4.4.5, 5.4, 6.3, 6.4	9.2, 4th dash	Any part of the sterilizer can be the object of maintenance and/or calibrated. Clause 6.4 of the present standard applies to any residual risk.
	9.3	Not likely to apply, see scope of this standard.
	10	Not likely to apply, see MEDDEV 2.1–5.
Table 5 (21), 6.2, 6.3	11	Including reference to EN 61326–1:2013; Steam sterilizers are neither intended, nor likely to generate or emit ionizing or any other radiation which might become hazardous.
4.4.4, 4.4.5, 4.5, 5.3, 6.1, 6.4	12.1	Including references to EN ISO 14971 and EN 61010–2-040: 2005, 7.104 and 14.104.
4.4.5, 4.5.4, 6.1, 6.4	12.1a)	State of the art comprehends many, in parts alternative standards. Reference is made to EN ISO 12100, EN 61508(series), EN 62061, and EN 62304.
6.2, 6.2.1	12.5	Reference is made to EN 61326–1:2013.
6.1	12.6	Reference is made to EN 61010–2-040:2005, Clauses 4, 5, 6, 11.6 and Clause 14.
4.3.1, 4.3.2, 4.3.5, 4.8, 6.1, 6.3, 6.4	12.7.1	Reference is also made to EN 61010–2-040:2005, Clauses 7, 8, 15
4.3.5	12.7.2	
4.3.6, 6.1	12.7.3	Reference is also made to EN 61010–2-040:2005, 12.5
4.3.1.5, Table 4 (12), 6.1	12.7.4	Reference is made to EN 61010–2-040:2005, 5.1.5, 5.4.3, 5.4.5, 6.5.2, 6.6, 6.10, 16.2 d)
4.9.2.2 b), 4.9.2.3 k), 6.1	12.7.5	Including reference to EN 61010–2-040:2005, Clause 10
4.4.1, 4.4.2, 4.4.3, 4.4.4, 4.5.3, Table 4 (31), 4.9.2.2, 6.1	12.9	Including reference to EN 61010–2-040:2005, 5.1.5
4.8, Table 4, 4.9, 6.1	13.1	Reference is made to EN 1041 and EN 61010–2-040:2005,

Clauses/sub-clauses of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
		Clause 5
4.8, 4.9.2.2, 6.1	13.2	Reference is also made to, EN 1041 and EN 61010–2-040:2005, 5.1.1
4.9.2.3	13.3 a), b), d), l)	
4.9.2.1, 4.9.2.2	13.3 i), j)	
4.9, 6.1, 6.3	13.3 k)	Reference is also made to EN 61010–2-040:2005, 5.1, 5.2, and further to EN 13445–5:2009, 11.4
4.8.1, Table 4 (2, 4, 8, 9, 23)	13.4	Reference is also made to EN 1041
4.9.2	13.5	
4.8, Table 4 (11, 25, 26, 27, 28, 32, 33, 34), 6.1, 6.3	13.6 a)	Including references to EN 1041, EN 61010–2-040: 2005, 5.1, 5.2, 5.3, and EN 13445–5:2009, 11.4
4.8.3, Table 4 (2, 5–10, 23, 24, 30, 34, 43)	13.6 b)	
4.8.4, Table 4 (11–16, 19–24, 28, 34, 48–50), 6.1	13.6 c)	Including references to EN 61010–2-040: 2005, 5.4.3, 5.4.4
4.8, Table 4 (5–7, 12, 15, 18, 31, 34, 35, 38–43, 47–50), 6.1	13.6 d)	Including references to EN 61010–2-040: 2005, 5.4.3, 5.4.4, 5.5.5
4.8.3, 4.8.4, Table 4 (28, 33), 6.2.1	13.6 f)	Including reference to EN 61326–1:2013, see also 12.5
1, 4.4.4, 4.8.1, 4.8.3, 4.8.4, Table 4 (4–6, 8, 17, 18, 27, 33, 35, 38, 41, 43), 7.1, Annex D, Table 5	13.6 i)	Note to the Scope refers to EN ISO 17665-1
4.8.3	13.6 q)	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this European Standard.

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following Table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 – Relevant Essential Health and Safety Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard (according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
4.2, 4.3, 4.7, Clause 6	1.1.3	
4.3.1	1.1.5	
4.3.2	1.3.9	
4.3.5	1.5.9	
Clause 4, Clause 6	1.1.6	
Clause 6	1.1.7, 1.3.4, 1.5.1, 1.5.2, 1.5.3, 1.5.5, 1.5.6, 1.5.8, 1.6.3	
4.3, 4.4.5, 4.5, Clause 6, Annex B	1.2.1	
4.4, Clause 6	1.2.2	
4.4, 4.5, Clause 6	1.2.3	
4.4, 4.5, Clause 6	1.2.4	
4.5	1.2.5	
4.3.2, 4.4.3, 4.5, Clause 6	1.2.6	
4.3.5, 4.8.1, 4.8.2, Clause 6	1.3.1	
4.3.2, 4.8, Clause 6	1.3.2	
4.3.1, Clause 6	1.3.3	
4.3.2, 4.8.2, Clause 6	1.3.7	
4.3.1, 4.3.3, 4.8.2	1.5.4	
4.2, Clause 6	1.5.13	
4.8.2, Clause 6	1.6.1	
4.4, Clause 6	1.6.2	
4.3.2, 4.5, 4.8.2	1.6.4	
4.8.2, Clause 6	1.7.1	
4.8, Clause 6	1.7.2, 1.7.3, 1.7.4	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this European Standard.

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EN 13445-5:2009, *Unfired pressure vessels — Part 5: Inspection and testing*

EN 60073, *Basic and safety principles for man-machine interface, marking and identification — Coding principles for indicators and actuators (IEC 60073)*

EN 60584-2, *Thermocouples — Part 2: Tolerances (IEC 60584-2)*

EN 61508 (all parts), *Functional safety of electrical/electronic/programmable electronic safety-related systems*

EN 61508-1, *Functional safety of electrical/electronic/programmable electronic safety-related systems — Part 1: General requirements (IEC 61508-1)*

EN 62061, *Safety of machinery — Functional safety of safety-related electrical, electronic and programmable electronic control systems (IEC 62061)*

EN 62304, *Medical device software — Software life-cycle processes (IEC 62304)*

EN ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary (ISO 9000:2005)*

EN ISO 10993 (all parts), *Biological evaluation of medical devices (ISO 10993 series)*

prEN ISO 11140-6, *Sterilization of health care products — Chemical indicators — Part 6: Class 2 indicators and process challenge devices for use in performance testing for small steam sterilizers (ISO/AWI 11140-6)* (in preparation)

EN ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1)*

EN ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2)*

EN ISO 12100, *Safety of machinery — General principles for design — Risk assessment and risk reduction (ISO 12100)*

EN ISO 13485:2012, *Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2003)*

EN ISO 14937, *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 (ISO 14937)*

EN ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

EN ISO 15883-1:2009, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006)*

EN ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664)*

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ISO/IEC Guide 51:1999, *Safety aspects — Guidelines for their inclusion in standards*

[1] 93/42/EEC, COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices

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