BRITISH STANDARD

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285:2006
+A2:2009

Sterilization — Steam sterilizers — Large sterilizers

ICS 11.080.10

BSI
British Standards

National foreword

This British Standard is the UK implementation of EN 285:2006+A2:2009. It supersedes BS EN 285:2006+A1:2008 which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to CEN text carry the number of the CEN amendment. For example, text altered by CEN amendment A1 is indicated by [A1⟩ ⟨A1].

The UK participation in its preparation was entrusted to Technical Committee LBI/35, Sterilizers, autoclaves and disinfectors.

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

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

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EUROPÄISCHE NORM

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English Version

Sterilization - Steam sterilizers - Large sterilizers

Stérilisation - Stérilisateurs à la vapeur d'eau - Grands stérilisateurs

Sterilisation - Dampf-Sterilisatoren - Groß-Sterilisatoren

This European Standard was approved by CEN on 27 April 2006 and includes Amendment 1 approved by CEN on 4 February 2008 and Amendment 2 approved by CEN on 5 April 2009.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Contents

Foreword

This document (EN 285:2006+A2:2009) 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 November 2009 and conflicting national standards shall be withdrawn at the latest by March 2010.

This document includes Amendment 1, approved by CEN on 2008-02-04 and Amendment 2, approved by CEN on 2009-04-05.

This document supersedes [A2] EN 285:2006+A1:2008 [/A2].

The start and finish of text introduced or altered by amendment is indicated in the text by tags [A1] [/A1] and [A2] [/A2].

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.

This document does not specify requirements for the validation and routine control of sterilization by moist heat. A European Standard specifying requirements for the validation and routine control of sterilization by moist heat was prepared by CEN/TC 204 "Sterilization of medical devices", see EN 554 (currently under revision, see prEN ISO 17665).

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 Creutzfeld-Jakob disease. However, some national regulations require the use of modified steam processes as part of a general prion decontamination programme.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

1 Scope

1.1 This European Standard specifies requirements and the relevant tests for large steam sterilizers primarily used in health care for the sterilization of medical devices and their accessories contained in one or more sterilization modules. The test loads described in this European Standard are selected to represent the majority of loads (i.e. wrapped goods consisting of metal, rubber and porous materials) for the evaluation of general purpose steam sterilizer for medical devices. However, specific loads (e.g. heavy metal objects or long and/or narrow lumen) will require the use of other test loads.

Large steam sterilizers can also be used during the commercial production of medical devices.

1.2 This European Standard is not applicable to steam sterilizers designed to process a size of load less than one sterilization module or having a chamber volume less than 60 l.

1.3 This European Standard does not describe a quality assurance system for the control of all stages of the manufacture of the sterilizer.

NOTE Attention is drawn to the standards for quality management systems e.g. EN ISO 13485.

1.4 Planning and design of products applying to this European Standard should consider the environmental impact from the product during its life cycle. Environmental aspects are addressed in Annex A.

NOTE Additional aspects of environmental impact are addressed in EN ISO 14971.

2 Normative references

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

EN 764-1:2004, *Pressure equipment — Part 1: Terminology — Pressure, temperature, volume, nominal size*

〚A1〛 *deleted text* 〚A1〛

EN 867-3, *Non-biological systems for use in sterilizers — Part 3: Specification for Class B indicators for use in the Bowie and Dick test*

〚A1〛 EN 867-5, *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* 〚A1〛

EN 868-5, *Packaging materials and systems for medical devices which are to be sterilized — Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction — Requirements and test methods*

EN 1822 (all parts), *High efficiency air filters (HEPA and ULPA)*

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

EN 10088-3, *Stainless steels — Part 3: Technical delivery conditions for semi-finished products, bars, rods, wire, sections and bright products of corrosion resistant steels for general purposes*

EN 12953 (all parts), *Shell boilers*

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

EN 14222, *Stainless steel shell boilers*

EN 60584-2:1993, *Thermocouples — Part 2: tolerances (IEC 60584-2:1982 + A1:1989)*

EN 60751:1995, *Industrial platinum resistance thermometer sensors (IEC 60751:1983 + A1:1986)*

EN 61010-1, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 1: General requirements (IEC 61010-1:2001)*

EN 61010-2-040, *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 61326:1997, *Electrical equipment for measurement, control and laboratory use — EMC requirements (IEC 61326:1997)*

EN 61672-1:2003, *Electroacoustics — Sound level meters — Part 1: Specifications (IEC 61672-1:2002)*

EN 61672-2:2003, *Electroacoustics — Sound level meters — Part 2: Pattern evaluation tests (IEC 61672-2:2003)*

EN ISO 3746:1995, *Acoustics — Determination of sound power levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane (ISO 3746:1995)*

EN ISO 4017, *Hexagon head screws — Product grades A and B (ISO 4017:1999)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 764-1:2004 and the following apply.

NOTE Other definitions relevant to validation are given in EN 554.

3.1
access device
means used to permit access to restricted parts of the equipment

NOTE This may be by dedicated key, code or tool.

3.2
air removal
removal of air from the sterilizer chamber and sterilizer load to facilitate steam penetration

3.3
automatic controller
device that, in response to pre-determined cycle variables, operates the sterilizer sequentially through the required stages of the cycle(s)

3.4
biological indicator
microbiological test system providing a defined resistance to a specified sterilization process

[ISO/TS 11139:2001, definition 2.4]

3.5
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 realized by standards

[IVM:1994, definition 6.11]

3.6
chamber depth
depth of the sterilizer chamber which is available for the sterilizer load

3.7
chamber height
height of the sterilizer chamber which is available for the sterilizer load

3.8
chamber width
width of the sterilizer chamber which is available for the sterilizer load

3.9
cycle complete
indication that the sterilization cycle has been completed according to programme and that the sterilized load is ready for removal from the sterilizer chamber

3.10
door
lid or similar device provided as a means of closing and sealing the sterilizer chamber

3.11
double ended sterilizer
sterilizer in which there is a door at each end of the sterilizer chamber

〖A1〗 **3.12**
endpoint
point of the observed change as defined by the manufacturer occurring after the indicator has been exposed to specified stated values

[EN ISO 11140-1:2005] 〈A1〗

3.13
equilibration time
period which elapses between the attainment of the sterilization temperature at the reference measurement point and the attainment of the sterilization temperature at all points within the load

3.14
holding time
period for which the temperatures at the reference measurement point and at all points within the load are continuously within the sterilization temperature band

NOTE The holding time follows immediately after the equilibration time. The extent of the holding time is related to the sterilization temperature.

3.15
inoculated carrier
carrier on which a defined number of test organisms has been deposited

[EN 866-1:1997, definition 3.8]

3.16
installation qualification
IQ
process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification

[ISO/TS 11139:2001, definition 2.20]

3.17
loading door
door in a double ended sterilizer through which the sterilizer load is put into the sterilizer chamber prior to sterilization

3.18
medical device
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

[EN ISO 13485:2003, definition 3.7]

3.19
non-condensable gas
air and other gas which will not condense under the conditions of steam sterilization

3.20
operating cycle
sequence of operating stages which is performed automatically by a sterilizer

3.21
operational qualification
OQ
process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

[ISO/TS 11139:2001, definition 2.24]

3.22
operator
person operating equipment for its intended purpose

3.23
plateau period
equilibration time plus the holding time

3.24
pressure vessel
vessel comprising the sterilizer chamber, jacket (if fitted), door(s) and components that are in permanent connection with the sterilizer chamber

[A1] 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 [A1]

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

3.27
reference standard
standard, generally having the highest metrological quality available at a given location or in a given organization, from which measurements made there are derived

[IVM:1994, definition 6.6]

3.28
saturated steam
water vapour in a state of equilibrium between condensation and evaporation

[ISO 13683:1997, definition 3.18]

3.29
sterile
condition of a medical device that is free from viable microorganisms

[EN 556-1:2001, definition 3.4]

3.30
sterilization
validated process used to render a product free from viable microorganisms

[ISO/TS 11139:2001, definition 2.42]

NOTE 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.

3.31
sterilization cycle
operating cycle performed by a sterilizer for the purpose of sterilization

3.32
sterilization module
rectangular parallelepiped of dimensions 300 mm (height) × 600 mm (length) × 300 mm (width)

3.33
sterilization temperature
minimum temperature on which the evaluation of the sterilization efficacy is based

3.34
sterilization temperature band
temperature tolerance range for the load and the reference measurement point, the minimum of which is the sterilization temperature

NOTE These temperatures are usually stated in whole degrees Celsius.

3.35
sterilizer
apparatus designed to achieve sterilization

3.36
sterilizer chamber
part of the sterilizer which receives the sterilizer load

[EN 554:1994, definition 3.27]

3.37
sterilizer load
items that are to be sterilized simultaneously in the same sterilizer chamber

3.38
superheated steam
water vapour whose temperature is higher than the boiling point of water at the corresponding pressure

3.39
test organism
microorganisms used for the manufacture of inoculated carriers

[EN 866-1:1997, definition 3.16]

3.40
type test
series of checks and tests for a particular design of sterilizer to demonstrate compliance with the requirements of this European Standard

3.41
unloading door
door in a double ended sterilizer through which the sterilizer load is removed from the sterilizer chamber after a sterilization cycle

3.42
usable space
space inside the sterilizer chamber which is not restricted by fixed parts and which is available to accept the sterilizer load

3.43
works test
series of tests performed at the manufacturer´s works to demonstrate that each sterilizer will comply with its specification

4 Mechanical components

4.1 Dimensions

The usable space within the sterilizer chamber shall accommodate one or more sterilization modules.

4.2 Materials

Materials in contact with steam shall:

— resist attack from steam and condensate;

— not cause deterioration of the quality of the steam;

— not release any substances known to be toxic in such quantities that could create a health or environmental hazard.

NOTE 1 Guidance on steam contaminants is given in Table B.2.

NOTE 2 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. The purchaser should provide the manufacturer with information about the goods to be sterilized.

NOTE 3 Advice on the various combinations of materials is given in Annex C. However, for some applications, a combination of materials selected from more than one group may be appropriate.

4.3 Pressure vessel

4.3.1 General

4.3.1.1 The pressure vessel shall comply with EN 13445.

4.3.1.2 The door seal shall be a replaceable component.

It shall be possible to inspect and clean the surface of the door seal which comes into contact with the sealing faces without the need to dismantle the door assembly.

4.3.1.3 After closing the sterilizer door, it shall be possible to open it before a cycle has been started.

4.3.1.4 It shall not be possible to open a sterilizer door(s) during a cycle.

4.3.2 Double ended sterilizers

4.3.2.1 Except for maintenance purposes it shall not be possible for more than one door to be open at one time.

4.3.2.2 It shall not be possible to open the unloading door until a cycle complete indication is obtained.

4.3.2.3 It shall not be possible to open the unloading door if a Bowie and Dick cycle or an air leakage test has been carried out (see 7.1.14 and 7.1.15).

4.3.2.4 The control used to start the sterilization cycle shall be located at the loading side of the sterilizer.

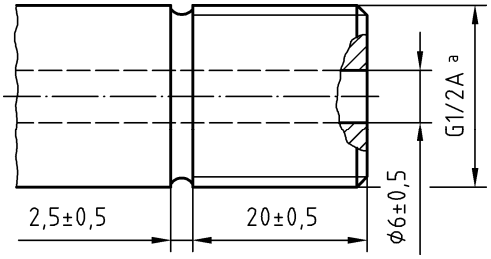
4.3.3 Test connections

4.3.3.1 The connections as required by 4.3.3.2 and 4.3.3.3 shall be provided.

NOTE The test connection for pressure test and temperature test as shown in Figure 1 and Figure 2 may be provided as a combined detachable adapter.

4.3.3.2 A test connection in accordance with Figure 1 shall be fitted to the sterilizer chamber or in a pipe which is in direct connection with the sterilizer chamber providing it causes no adverse effect on the measurement of the pressure in the sterilizer chamber. The test connection which is used for the connection of a test instrument shall be provided with a cap, marked PT (pressure test) and sealed with either an O-ring-seal or a flat seal.

Dimensions in millimetres



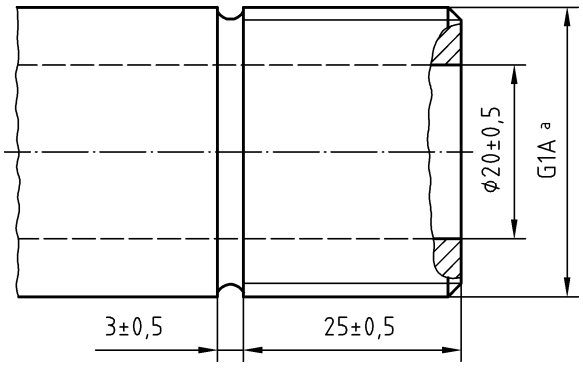
Key

[a] Pipe thread EN ISO 228-G 1/2 A

Figure 1 — Connection for test instrument

4.3.3.3 A straight connecting sleeve, in accordance with Figure 2, shall be provided at a point of easy access in order to pass flexible cords to the temperature sensors.

Dimensions in millimetres



Key

[a] Pipe thread EN ISO 228-G 1 A

Figure 2 — Connection sleeve for thermoelements

The connecting sleeve with its O-ring-seal or flat seal shall be closed with a cap, and a temperature proof and mechanically resistant soft packing. The cap shall be marked with the letters TT (temperature test).

4.3.3.4 Test tee(s) and valve cock(s) with sealing plug(s) shall be fitted to permit connection of reference instruments for the calibration of all pressure instruments, connected to the sterilizer chamber and jacket (see 6.1.2 and 6.1.4).

4.3.4 Insulating material

Except where insulation would interfere with the function and operation of the sterilizer, external surfaces of the pressure vessel shall be insulated to reduce heat transmission to the environment [see also 26.2 g) and h)].

4.4 Framework and panelling

4.4.1 Where the sides of the sterilizer are visible from the operator area, they shall be enclosed with panelling. The manufacturer shall provide instructions for the cleaning of the panelling.

NOTE The panelling should have a corrosion-resistant finish to the cleaning agents specified by the manufacturer.

4.4.2 The panelling of the sterilizer shall allow access for maintenance work. Such panelling shall be demountable or the dimensions of any personal access shall be not less than 500 mm wide and not less than 1 500 mm high, and the access shall not be obstructed.

NOTE 1 If the pressure equipment is housed in a frame, this frame should not promote corrosion of the equipment.

NOTE 2 The access for maintenance should be positioned so that it will not compromise the safety of either the product or persons.

NOTE 3 Requirements for access are specified in EN 61010-2-040.

4.4.3 The panelling shall be designed to provide a continuous contact with the surfaces of the building in which it is installed when these surfaces are within the tolerances given in Tables 1 and 2.

Sterilizers designed for incorporation into existing buildings, or purpose built rooms shall provide a continuous joint with adjacent surfaces when these are within the limits given in Tables 1 and 2.

Table 1 — Tolerances for the aperture into which the sterilizer is installed

Dimension m	**Tolerance** mm	
	Horizontal plane	Vertical plane
up to 3	± 12	± 16
above 3 to 6	± 16	± 16
above 6 to 15	± 24	± 20
above 15 to 30	± 24	± 20
above 30	± 30	± 30

Table 2 — Deviation from vertical and horizontal flatness and alignment

Distance between checkpoints m	Deviation mm	
	Finished surfaces of walls and ceilings	Finished floor (bearing surface)
0,1	3	2
1	5	4
4	10	10
10	20	12
15	25	15

5 Process components

5.1 Pipework and fittings

5.1.1 Pipe joints and fittings shall be both pressure-tight and vacuum-tight.

5.1.2 Except where this will interfere with the function of the sterilizer the pipework for steam or water at a temperature greater than 60 °C shall be thermally insulated to reduce heat transmission to the environment [see also 26.2 g) and h)].

NOTE To reduce the formation of condensation cold water pipework should be insulated.

5.1.3 Means shall be provided to prevent the ingress of particulates of a size and quantity which could affect the performance of a sterilizer.

NOTE Strainers of a relevant pore size may be used.

5.1.4 All control valves in the pipework shall be marked with permanent identification in relation to their functions (see 12.2).

NOTE Reference numbers or written descriptions can be used.

5.2 Steam source

5.2.1 General

A sterilizer can be operated with steam from an external supply, or generated solely for the sterilizer or a group of sterilizers, or generated from within the sterilizer chamber.

5.2.2 Steam supply from a dedicated steam generator

5.2.2.1 Shell boilers shall comply with EN 14222 or EN 12953 as applicable.

5.2.2.2 The feed water inlet shall be designed to prevent back-syphoning into the feed water system.

NOTE This may require the use of a break tank which should be made from material resistant to water at 100 °C.

5.2.2.3 The power requirements and the capacity of the steam generator shall be sufficient to ensure that the steam demand specified for the sterilizer can be met.

5.2.2.4 The manufacturer shall specify the quality and quantity of feed water (see 13.3.7, 26.2 e) and m) and Table B.1).

5.2.3 Steam supply from a central source

The manufacturer shall specify the quality and quantity of the steam to be supplied for use with the sterilizer [see 26.2 d)].

NOTE See Table B.2 for guidance on condensate derived from the steam.

5.3 Air filter

5.3.1 Where the sterilization cycle requires the admission of air into the sterilizer chamber, the air shall be admitted through a filter.

NOTE Air filters should be constructed from material resistant to corrosion and biodegradation. The filter material should be supported in a manner which prevents damage to the filter medium.

5.3.2 The filter shall comply with class H 14 in accordance with EN 1822 or better and the most penetrating particle size shall be 0,3 µm or smaller when tested in accordance with EN 1822.

5.3.3 The filter unit shall be accessible, replaceable and mounted externally to the sterilizer chamber in such a manner that the filter material is kept dry.

5.3.4 Means shall be provided to prevent the penetration of steam, water and/or condensate from the sterilizer chamber into the filter.

5.4 Vacuum system

A vacuum system shall be used for air removal and drying. The manufacturer shall specify the depth of vacuum needed to comply with the requirements for the tests specified in this European Standard [see 26.2 r)].

6 Instrumentation, indicating and recording devices

6.1 Equipment

6.1.1 General

6.1.1.1 All instruments and indicating devices specified in Clause 6 shall be located in a position where they can be readily viewed by the operator under normal operation of the sterilizer and their function shall be identified.

6.1.1.2 Unless otherwise specified instruments and gauges shall be readable by normal or corrected vision from a distance of (1,00 ± 0,15) m and with a minimum external illumination of (215 ± 15) lx.

6.1.1.3 Each instrument and gauge shall be located in a manner that ensures that the maximum and minimum values of temperature and humidity specified by the instrument and gauge manufacturers are not exceeded during normal operation.

NOTE Normally the temperature and relative humidity in the vicinity of instruments and gauges should not exceed 50 °C and 85 % respectively.

6.1.2 Instruments

Sterilizers shall be provided with at least the following instruments:

a) sterilizer chamber temperature indicating instrument;

b) sterilizer chamber temperature recorder;

c) sterilizer chamber pressure indicating instrument;

d) sterilizer chamber pressure recorder;

e) jacket pressure indicating instrument (if the sterilizer is fitted with a jacket intended to be pressurized);

f) steam pressure gauge (if a steam generator is incorporated within the sterilizer panelling).

NOTE 1 Items b) and d) may be incorporated into a single recording system.

NOTE 2 Except where required in EN 61010-2-040 the instruments a), c), e) and f) may be incorporated into a system whereby the display of any measurement may be selected by the user.

6.1.3 Indicating devices

6.1.3.1 Sterilizers shall be provided with at least the following indicating devices:

a) visual display indicating "door(s) locked";

b) visual display indicating "in progress";

c) visual display indicating "cycle complete";

d) visual display indicating "fault" (see 7.2);

e) indication of the operating cycle selected;

f) operating cycle counter;

g) operating cycle stage indication.

NOTE The operating cycle stage indication may incorporate items a), b) and c).

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

6.1.4 Double ended sterilizer

Both ends of the sterilizer shall be provided with at least:

a) sterilizer chamber pressure indicating instrument;

b) visual display indicating "doors locked";

c) visual display indicating "in progress";

d) visual display indicating "cycle complete";

e) visual display indicating "fault" (see 7.2).

6.2 Sensors, indicating instruments and time equipment

6.2.1 Temperature

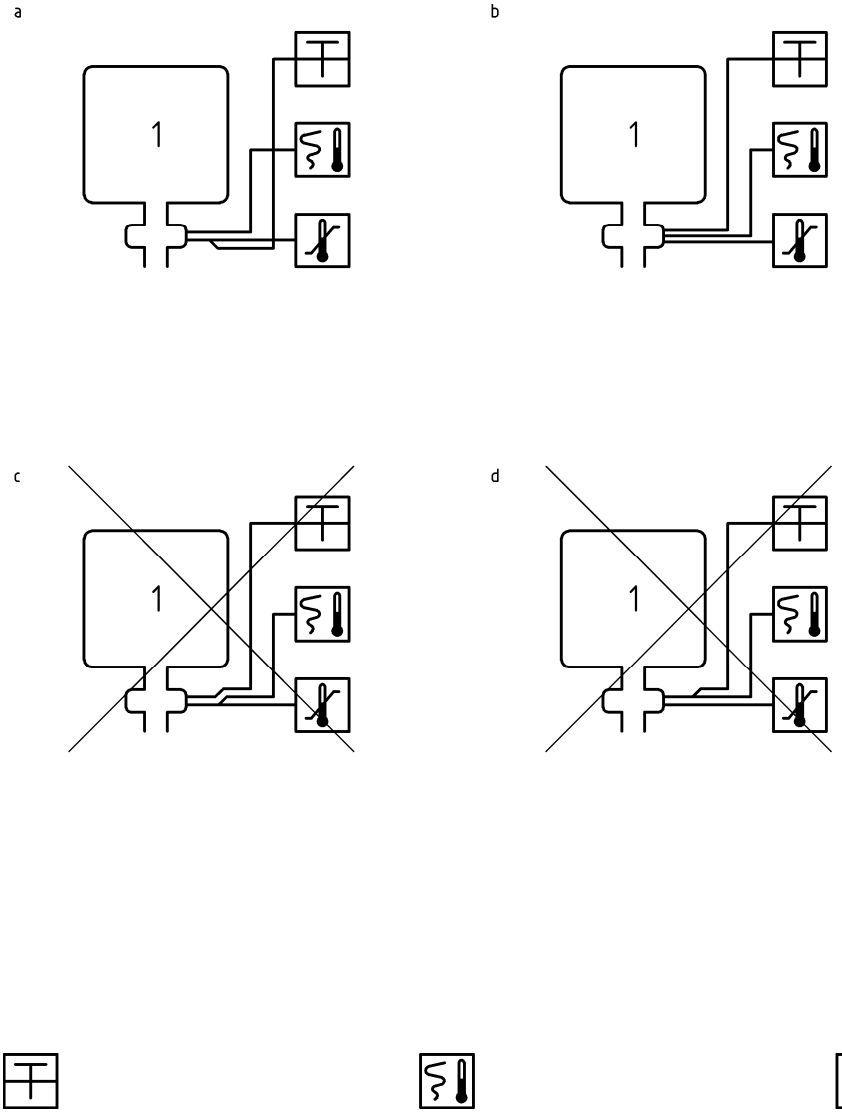
6.2.1.1 Temperature sensors

Temperature sensors shall be either platinum resistance types complying with Class A of EN 60751:1995 or thermocouples complying with one of the tables specified in Tolerance Class 1 of EN 60584-2:1993.

NOTE Other sensors of demonstrated equivalence can be used.

The temperature sensor shall have a response time $\tau_{90} \leq 5$ s when tested in water.

At least two independent temperature sensors shall be provided. These sensors shall be connected to the sterilizer chamber temperature indicating instrument, temperature recorder and temperature controller as indicated in Figure 3 a) or b). The arrangement illustrated in Figure 3 c) and d) shall not be permitted.



Sterilizer chamber temperature indicating instrument | Temperature recorder | Control and/or monitoring of plateau period by temperature

Key

1 sterilizer chamber

Figure 3 — Possible arrangement of temperature sensors

The sensor used for the control of the sterilization cycle and for the indication and also the sensor used to record the sterilization cycle shall be located at the point identified by the manufacturer as the reference measurement point (see 7.1.4).

6.2.1.2 Moveable temperature sensors inside sterilizers

Where a moveable temperature sensor and its wiring is located inside the sterilizer chamber, it shall be manufactured in such a way as to be temperature resistant as well as pressure-tight, vacuum-tight and steam-tight.

6.2.1.3 Sterilizer chamber temperature indicating instrument

The sterilizer chamber temperature indicating instrument shall:

a) be either digital or analogue;

b) be graduated in degrees Celsius;

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

f) for digital instruments have a resolution of 0,1 °C or better;

g) be adjusted to an accuracy of ± 0,5 °C or better at the sterilization temperature;

h) have an ambient temperature error compensation not exceeding 0,04 K/K;

i) have means to adjust in situ by the use of an access device without dismantling the instrument.

6.2.2 Pressure

The sterilizer chamber 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 0 kPa to 400 kPa or - 1 bar to 3 bar with a zero reading at absolute vacuum or 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) for analogue instruments be graduated in divisions not greater than 20 kPa (0,2 bar);

f) for digital instruments have a resolution of 1 kPa (0,01 bar) or better;

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

h) have an ambient temperature error compensation not exceeding 0,04 %/K over the scale range 0 kPa to 400 kPa (- 1 bar to 3 bar);

i) have means to adjust in situ by the use of an access device without dismantling the instrument.

NOTE Where digital pressure indicators are used, an additional mechanically actuated indicator can be required to comply with national pressure vessel regulations. Where an analogue instrument is provided only for this purpose, the requirement for adjustment in situ is waived.

6.2.3 Time indicating equipment

If time indicators are fitted they shall:

a) be graduated in hours, minutes and seconds as applicable;

b) have an error not exceeding 1 %.

6.3 Recorders and records

6.3.1 General

6.3.1.1 The recorder shall be either analogue or digital.

6.3.1.2 The recorder shall be independent such that the measuring chain as well as value data processing and printed values are separate from the automatic controller.

NOTE This does not exclude the transfer of informative data from the automatic controller to the recorder and vice versa, via a combined system for data transfer.

6.3.1.3 Records shall include the values for the pressure transition points throughout the operating cycle. The printing of data shall be sufficient to confirm that the cycle parameters have been attained and maintained within the permitted tolerances throughout the operating cycle (see also Clause 8).

NOTE Figure 4 and Table 3 illustrate the points where cycle variables should be recorded for a specimen sterilization cycle.

6.3.1.4 The recorder shall produce a record which shall be readable as defined in 6.3.1.5 when stored in defined conditions for a period of not less than 11 years.

6.3.1.5 Records shall be readable when viewed at a distance of (250 ± 25) mm with normal or corrected vision in an illumination of (215 ± 15) lx.

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

Time periods up to 5 min shall have an accuracy of ± 2,5 % or better and for periods above 5 min of ± 1 % or better.

6.3.1.7 Means shall be provided to adjust the recorder in situ by the use of an access device.

6.3.2 Recorders producing analogue records

6.3.2.1 Chart speed

Recorders producing analogue records shall have a chart speed of not less than 4 mm/min.

6.3.2.2 Temperature

Temperature recorders producing analogue records shall:

a) have a chart graduated in degrees Celsius;

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

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

d) have a chart with graduated divisions not greater than 2 °C;

e) have a resolution of 1 °C or better;

f) be adjusted to an accuracy of ± 1 °C or better at the sterilization temperature;

g) have a sampling rate for each channel of 2,5 s or better.

6.3.2.3 Pressure

Pressure recorders producing analogue records shall:

a) have a chart graduated in kilopascals or bars;

b) have a scale which includes the range 0 kPa to 400 kPa or - 1 bar to 3 bar with a zero reading at absolute vacuum or ambient pressure respectively;

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

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

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

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

g) have a sampling rate for each channel of 1 s or better.

6.3.3 Recorders producing digital records

6.3.3.1 Temperature

Temperature recorders producing digital records shall:

a) have alphanumeric characters;

b) have data defined by text;

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

d) have a resolution of 0,1 °C or better;

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

f) have a paper width which has a space for a minimum of 15 characters/line;

g) have a sampling rate for each channel of 2,5 s or better.

6.3.3.2 Pressure

Pressure recorders producing digital records shall:

a) have alphanumeric characters;

b) have data defined by text;

c) have a range which includes 0 kPa to 400 kPa (- 1 bar to 3 bar);

d) have a resolution of 1 kPa (0,01 bar) or better;

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

f) have a paper width which has a space for a minimum of 15 characters/line;

g) have a sampling rate for each channel of 1 s or better.

Table 3 — Examples of values to be recorded

Programme step	Time	Temperature (measured value)	Pressure (measured value)	Sterilization [a]		Date [a] and sterilizer identification
				Cycle identification	Counter No	
ON	X					X
START	X			X	X	X
t_1	X		X [b]			
t_2	X		X [b]			
t_3	X	X	X			
t_4	X	X	X			
t_5	X		X			
t_6	X		X			
END	X					
OFF	X					

a Optional for analogue records

b For each change:

t_1 time at the start of the first steam injection;

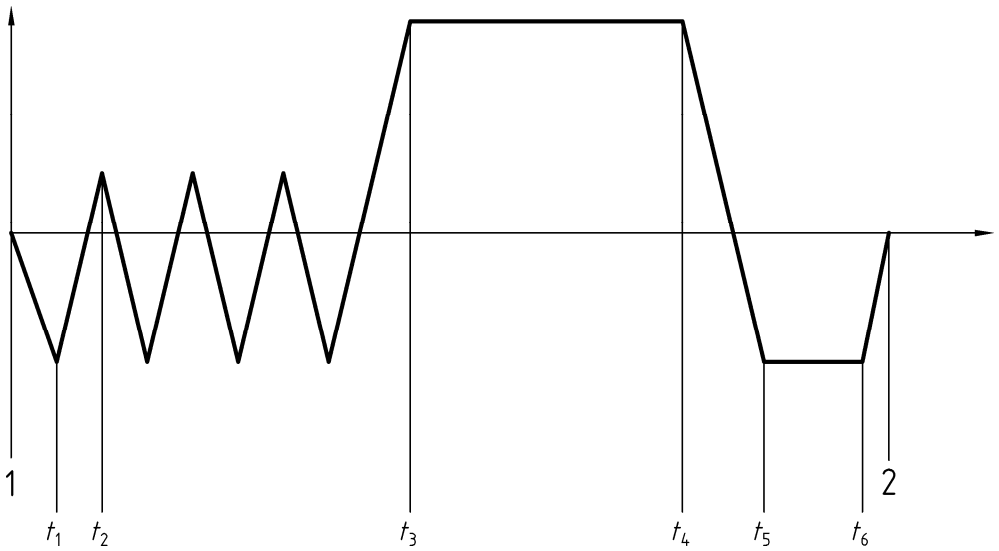
t_2 time at the start of the second vacuum pulse;

t_3 time at the start of the plateau period;

t_4 time at the end of the holding time;

t_5 time at the start of the drying period;

t_6 time at the end of the drying period.



Key

1 start 2 end

Figure 4 — Diagram of a specimen sterilization cycle given as an example only

7 Control systems

7.1 General

7.1.1 The sterilizer shall be operated by an automatic controller which has one or more pre-set operating cycles.

NOTE 1 The user may specify the use of an access device for the selection and/or starting of the cycle(s) used for production or test.

NOTE 2 Automatic loading and unloading can be performed before the sterilization cycle start and after a cycle complete.

7.1.2 The parameters identified by the manufacturer as critical to the sterilization process shall be reproducible within the limits identified in 7.1.3. This shall be demonstrated by the tests specified in this European Standard.

7.1.3 The manufacturer shall specify the parameters programmed into the automatic controller and the tolerances that will ensure the performance requirements in ⟩A1⟨ 8.2 ⟩A1⟨ to be met.

NOTE See Figure 4 and Table 3.

7.1.4 The reference measurement point shall be selected in such a way that throughout the plateau period the temperature at this point correlates with the temperature in the usable space.

The temperature relationship between the reference measurement point selected and the location identified as the coolest part of the usable space shall be determined.

7.1.5 A device shall be fitted such that if a failure of the automatic controller occurs, the pressure within the sterilizer chamber can be returned to atmospheric pressure to allow the loading door to be safely opened.

7.1.6 Measurement systems for sterilizer chamber temperature and pressure shall be fitted with broken sensor monitoring (see 7.2.4) which will cause a fault to be indicated.

7.1.7 The error of any controlled time period shall not exceed 1 % of the specified value.

7.1.8 The adjustment of control settings shall only be possible by the use of an access device.

7.1.9 For maintenance, test purposes and in cases of emergency, means shall be provided to permit the sequential manual progression of each stage of the cycle. The selection of this manual facility shall be by means of an access device different from the one specified above (see Clause 11).

The selection of the manual advance system shall be indicated.

7.1.10 The sterilizer shall be protected against effects of short circuit in inputs and outputs that are connected to the automatic controller.

7.1.11 The automatic controller shall have a status indicator for each digital input and output.

NOTE This can be located within the control cabinet.

7.1.12 Means shall be provided to ensure that a failure to attain the parameters specified in 7.1.3 will be detected for each subsequent sterilization cycle used for production or test.

7.1.13 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 to the plateau period used for the sterilization cycle used for production ⟩A1⟨ *deleted text* ⟩A1⟨. 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 867-3 and EN 867-4.

7.1.14 An automatic test cycle shall be provided to carry out the air leakage test (see Clause 18).

The error in measurement for a pressure difference of any 1,5 kPa (15 mbar) shall not exceed 0,1 kPa (1 mbar) over the pressure range that may occur during the test.

7.1.15 Whenever a test cycle is provided the indication at the end of the cycle shall be different from that of the sterilization cycle used for production.

7.2 Fault indication system

7.2.1 If the values of cycle variables are outside the limits specified by the manufacturer (see 7.1.3), or a failure of a service occurs sufficient to prevent the attainment of these variables or the shut down device has been operated, the automatic controller shall:

a) cause a visual indication that a fault has occurred;

NOTE 1 Additionally, an audible alarm system which should be mutable can be provided.

b) cause a visual indication of the stage of the sterilization cycle at which the fault occurred.

NOTE 2 Additional requirements for safety are specified in EN 61010-1.

7.2.2 If the sterilizer is fitted with a printer, the indication of a fault shall be distinguishable.

7.2.3 After a fault has been indicated a visual display of the fault shall continue at least until the door locking mechanism is released by the use of an access device.

NOTE It should be assumed that the sterilizer load has not been subjected to the sterilization cycle.

7.2.4 When a broken sensor occurs the monitoring system shall cause a fault to be indicated (see 7.1.6).

8 Performance requirements

8.1 Steam penetration

8.1.1 When tested in accordance with 16.1, the result shall be in accordance with [A1] 8.2.1.2 [A1].

8.1.2 When tested in accordance with 16.2, the result shall be in accordance with [A1] 8.2.1.3 [A1].

8.1.3 When tested in accordance with Clause 17, the result shall be in accordance with [A1] 8.2.2 [A1].

NOTE 1 Each steam sterilization process is a unique event. Whilst a steam penetration test carried out on a periodic basis provides a very useful equipment control function provision should be made to ensure adequate steam penetration occurs during every cycle.

[A1] NOTE 2 In healthcare there has been an increase in the use of instruments with long lumens. For some of these instruments the air removal efficacy identified by the tests based on textile loads may be inadequate. These tests have their origin in the steam penetration test using a textile pack[1)]. It was designed to establish that at the commencement of the plateau period, air removal had been sufficient to achieve a vapour temperature throughout a textile load equivalent to the vapour pressure of the steam in the sterilizer chamber. The hollow load test complements these tests and should be regarded as an addition to, and not as a replacement to them. A successful hollow load test indicates adequate air removal and even steam penetration into a process challenge device. A failure of any steam penetration test can be caused by an inefficient air removal stage, the presence of an air leak into the sterilizer chamber, and/or the presence of non-condensable gases in the steam supply. [A1]

1) See Bowie, J. H., Kelsey, J. C. and Thompson, G. R., Lancet i, p. 586, 1963

NOTE 3 If the sterilization process relies on the removal of air from the sterilizer chamber in order to achieve rapid and even penetration of steam into the sterilizer load, conformity with the performance requirements for the steam penetration test specified in this European Standard indirectly establishes the air dilution generated by the sterilization process. Conformity should be regarded as a pre-requisite for the definition of process parameters as required by prEN ISO 17665 for the range of products (e.g. hollow products and lumen) a sterilizer conforming to this European Standard is intended to process.

〚A1〛 **8.1.4** When tested in accordance with Clause 15, the result shall be in accordance with 8.2.5. 〚A1〛

〚A1〛 *deleted text* 〚A1〛

8.2 Physical parameters

8.2.1 Temperature characteristics

8.2.1.1 Sterilization temperature band

The sterilization temperature band shall have the lower limit defined by the sterilization temperature and an upper limit of + 3 °C (see also Figure D.1).

Compliance shall be tested in accordance with 16.1 and 16.2 respectively.

8.2.1.2 Small load, thermometric

8.2.1.2.1 The equilibration time shall not exceed 15 s for sterilizer chambers up to 800 l usable space and 30 s for larger sterilizer chambers.

8.2.1.2.2 During the plateau period the temperature measured above the test pack (see 16.1) 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 (see also Figure D.1).

8.2.1.2.3 Throughout the holding time the temperature measured at the reference measurement point of the sterilizer chamber, any temperature measured within the test pack and the saturated steam temperature calculated from the measured chamber pressure shall:

— be within the sterilization temperature band;

— not differ from another by more than 2 °C.

See also Figure D.1.

The saturated steam temperature shall be calculated from the following equation:

$$T = A + B\,(InP + C)^{-1}\ ^{2)} \qquad (1)$$

where

T is the saturated 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.

2) IRVINE TH.F., LILEY, P.E., Steam and Gas tables with computer equations. *Academic Press*, 1984. See also IAPWS (International Association for the Properties of Water and Steam) at http://www.iapws.org

8.2.1.2.4 The holding time shall be not less than 15 min, 10 min and 3 min for sterilization temperatures of 121 °C, 126 °C and 134 °C respectively.

NOTE Other combinations of temperature and time may be required.

8.2.1.2.5 Compliance with [A1] 8.2.1.2.1 [A1] to [A1] 8.2.1.2.4 [A1] shall be tested in accordance with 16.1.

8.2.1.3 Full load, thermometric

8.2.1.3.1 The equilibration time shall not exceed 15 s for sterilizer chambers up to 800 l usable space and 30 s for larger sterilizer chambers.

8.2.1.3.2 At the end of the equilibration time, the temperature measured at the reference measurement point of the sterilizer chamber and the temperature measured at the nominal geometric centre and below the top sheet of a standard test pack (see 24.1) located in the test load shall be within the sterilization temperature band.

8.2.1.3.3 Throughout the holding time the temperature measured at the reference measurement point of the sterilizer chamber, any temperature measured within the test pack and the saturated steam temperature calculated from the measured chamber pressure shall:

— be within the sterilization temperature band;

— not differ from one another by more than 2 °C.

The saturated steam temperature shall be calculated from Equation (1).

8.2.1.3.4 The holding time shall be not less than 15 min, 10 min and 3 min for sterilization temperatures of 121 °C, 126 °C and 134 °C respectively.

NOTE Other combinations of temperature and time may be required.

8.2.1.3.5 Compliance with [A1] 8.2.1.3.1 [A1] to [A1] 8.2.1.3.4 [A1] shall be tested in accordance with 16.2.

8.2.2 Bowie and Dick test

When the sterilizer is tested as described in Clause 17 the indicator shall show uniform colour change throughout the indicator in accordance with EN 867-3 and the manufacturer's instructions.

8.2.3 Air leakage flow rate

When the sterilizer is tested as described in Clause 18 the rate of pressure rise shall be within the limits specified by the manufacturer and in any case shall be not greater than 0,13 kPa/min (1,3 mbar/min).

8.2.4 Air detector

8.2.4.1 General

If an air detector is fitted the performance requirements in [A1] 8.2.4.2 [A1] to [A1] 8.2.4.4 [A1] shall apply.

8.2.4.2 Air detector, small load

When tested as described in 19.2 an air detector shall cause a fault to be indicated if the volume of air or other non-condensable gases retained or introduced into the sterilizer chamber during the air removal and steam admission of the sterilization cycle causes a difference in temperature between the [A1] lowest measured temperature in [A1] a standard test pack (see 24.1) or reduced pack (see 24.2), as appropriate, and the temperature measured at the reference measurement point of the sterilizer chamber of more than 2 °C at the commencement of the equilibration time.

8.2.4.3 Air detector, full load

When tested as described in 19.3 an air detector shall cause a fault to be indicated if the volume of air or other non-condensable gases retained or introduced into the sterilizer chamber during the air removal and steam admission of the sterilization cycle causes a difference in temperature between the [A1] lowest measured temperature in [A1] a standard test pack (see 24.1) and the temperature measured at the reference measurement point of the sterilizer chamber of more than 2 °C at the commencement of the equilibration time.

8.2.4.4 Air detector function

When the sterilizer is tested as described in 19.4 the test result shall be regarded as satisfactory if a fault is indicated.

8.2.5 [A1] Hollow load test

When the sterilizer is tested in accordance with Clause 15, the indicator system shall have reached its endpoint as described by the manufacturer of the indicator system. [A1]

8.3 Load dryness

8.3.1 Load dryness, small load, textiles

When the sterilizer is tested as described in 20.1, the mass of the test pack shall not increase by more than 1 %.

8.3.2 Load dryness, full load, textiles

When the sterilizer is tested as described in 20.2, the mass of the standard test pack shall not increase by more than 1 %.

8.3.3 Load dryness, metal

When the sterilizer is tested as described in 20.3, the mass of the test load shall not increase by more than 0,2 %.

9 Sound power

The A-weighted sound power level and the maximum impulsive noise index shall be determined and specified for each type of sterilizer. For testing and calculation Clause 21 of this European Standard and EN ISO 3746:1995 shall apply (see also EN 61010-1). The upper level of both measurement uncertainty and production variation shall be stated.

If changes or modification of tested equipment have previously been identified as not contributing to more than 3 dB(A) to the total sound power level, further testing and change of the specification can be omitted.

NOTE 1 Other methods of demonstrated equivalence may be used.

The sound power level for any additional devices supplied by the sterilizer manufacturer for use with the sterilizer shall be specified.

NOTE 2 National legislation requires the perceived noise (sound pressure) in the working environment to be controlled. Sound pressure levels sensed in a room are a function of the sound power generated by the source, e.g. sterilizer, and the acoustic design of the room in which the source is installed. The purpose of specifying sound power is to ensure that the A-weighted sound power level and the maximum impulsive noise index is known and available for the design of the installation.

10 Rate of pressure change

The average pressure change for any 3 s interval during the sterilization cycle shall not exceed 1 000 kPa/min (10 bar/min). Compliance shall be tested as described in Clause 23.

NOTE This level is used as a performance requirement for packaging materials complying with EN 868 and has been chosen on the basis of a compromise between the need to provide cost effective packaging and short efficacious sterilization cycles.

11 Safety

Sterilizers shall comply with EN 61010-2-040 and EN 13445.

12 Marking

12.1 Markings for safety shall comply with EN 61010-1, EN 61010-2-040 and EN 13445.

12.2 Other markings shall be permanently and legibly marked and include at least:

— name/company and address of the manufacturer;

NOTE If the manufacturer is located outside the EU the person or organisation within the EU responsible for supplying the sterilizer should also be identified.

— unique identification number;

— model identification;

— production year (not required if this is included in the identification markings);

— description of the sterilizer as being a "steam sterilizer for wrapped goods and porous loads";

— control valve identification (see 5.1.4).

13 Service and local environment

13.1 General

Sterilizers complying with this European Standard shall meet the requirements of this European Standard when supplied with services meeting the following requirements.

NOTE The performance of a sterilizer is dependent upon its design and construction together with the quality of services provided. When services do not meet the specified requirements the performance of the sterilizer may be affected adversely.

13.2 Electrical supply

The sterilizer shall be designed to operate with an electrical supply in accordance with EN 61010-2-040 [see 26.2 b)].

13.3 Steam supply to the sterilizer chamber

13.3.1 General

The sterilizer shall be designed to operate with a steam supply that is provided with a condensate trap within 2 m of the connection to the sterilizer.

13.3.2 Non-condensable gases

The sterilizer shall be designed to operate with saturated steam containing up to 3,5 % V/V of non-condensable gases when tested as described in 22.1.

13.3.3 Dryness value

The sterilizer shall be designed to operate with saturated steam with a dryness value down to 0,95 for metal loads and 0,90 for other types of load when tested as described in 22.2.

13.3.4 Superheat

When the supplied steam is expanded to atmospheric pressure the superheat shall not exceed 25 °C when tested in accordance with 22.3.

13.3.5 Contaminants

The sterilizer shall be designed to operate with steam that does not contain contaminants in sufficient quantity to impair the sterilization process or harm or contaminate the sterilizer or sterilized load.

NOTE 1 Suggested maximum values of some contaminants are given in Table B.2 and Table E.2.

NOTE 2 A method for obtaining a condensate sample is given in 22.4.

13.3.6 Pressure fluctuation

The sterilizer shall be designed to operate with a pressure fluctuation not exceeding ± 10 % of the nominal gauge pressure measured at the inlet to the final pressure reduction valve.

13.3.7 Feed water

The sterilizer shall be designed to operate with steam produced from water free from contaminants in a concentration that can impair the sterilization process or harm or contaminate the sterilizer or sterilized load.

NOTE 1 Suggested maximum values of some contaminants are given in Annex B.

NOTE 2 Non-condensable gases dissolved in the feed water may cause an increase in non-condensable gases in the steam, see 13.3.2.

13.4 Water

The sterilizer shall be designed to operate with water that is of potable quality and supplied at a temperature not exceeding 15 °C.

NOTE 1 The temperature of water should be as low as possible because of the effect of temperature on the performance of the vacuum system. Higher water temperatures will affect the final vacuum level attained.

NOTE 2 The hardness value of water, Σ(ions of alkaline earth), should be between 0,7 mmol/l and 2,0 mmol/l. Hardness values outside these limits can cause scaling and corrosion problems.

NOTE 3 A backflow protection device in accordance with EN 1717 may be required.

13.5 Compressed air

The sterilizer shall be designed to operate with a compressed air supply at a pressure of 600 kPa to 800 kPa (5 bar to 7 bar), free of liquid water, filtered to 25 µm and free from oil droplets greater than 2 µm [see 26.2 e)].

13.6 Electromagnetic interference

13.6.1 Sterilizers shall comply with EN 61326:1997 regarding electromagnetic compatibility (EMC).

13.6.2 Sterilizers shall be regarded as class A equipment as specified in EN 61326:1997 unless operating in areas in which medical electrical equipment is used or in the vicinity in which other sensitive electronic equipment is located. For these sterilizers class B equipment as specified in EN 61326:1997 applies.

13.6.3 For immunity, the testing requirements in EN 61326:1997, Table A.1 apply.

For selection of immunity testing performance criteria, the general guidance rules of EN 61326:1997 apply.

13.6.4 The performance criteria selected shall ensure the sterilizer performance as specified in 7.1.2 will be met during normal operation, when exposed to disturbance phenomena given in EN 61326:1997, Table A.1.

13.7 Drains

The sterilizer shall be designed to operate with a drainage system resistant to water at 100 °C, and be capable of passing the maximum flow rate of water, air and condensed steam.

NOTE National regulations can require the drain be trapped and vented and not connected to other drains, which can cause a back pressure or obstruction to flow. An air break can also be necessary.

13.8 Supporting surface (floors)

The sterilizer shall be designed to operate when installed on a surface which is horizontal within the tolerance limits specified in Tables 1 and 2 (see 4.4) and which will support the maximum floor loading specified by the manufacturer [see 26.2 a)].

NOTE The floor should be impervious to water and adequate to collect or drain water spillage from the sterilizer.

13.9 Environment

The sterilizer shall be designed to operate in an ambient temperature and humidity as specified in EN 61010-1.

NOTE This can require the provision of a ventilation system designed and constructed to remove the heat transmitted from the sterilizer and from the sterilized load during unloading (see 6.1.1.3).

13.10 Service connections

The sterilizer shall be designed to operate with all service connections for fluids (e.g. water, steam, compressed air) provided with an isolating valve and terminating in accordance with the manufacturer's sterilizer specification.

14 Testing

14.1 General

14.1.1 Documentary evidence that the sterilizer complies with the requirements of this European Standard shall be established, maintained and declared (see also Clause 25).

NOTE 1 The tests described in Clauses 15 to 23 are reference tests intended for use in demonstrating conformity with the performance requirements specified in this European Standard. They may be used in type tests, works tests, in validation and re-validation tests, or in periodic and routine tests carried out by the user. Reproducibility should be demonstrated by consecutive triplicate tests (see also Annex E.)

NOTE 2 A recommended test programme to demonstrate conformity with the performance requirements of this European Standard is identified in Table 4.

NOTE 3 Requirements and guidance on validation and re-validation are given in prEN ISO 17665.

14.1.2 If adjustment is made to the sterilizer during a test sequence such that the cycle variables of the sterilization cycle are affected, the sequence of tests shall be repeated.

NOTE Changes to cycle parameters will normally be identified during thermometric testing.

Table 4 — Recommended test programme

Test	Requirement according to	Test method according to	Type test (see Annex F)	Works test
[A1] *deleted text* [A1]				
Themometric tests				
– Small load	[A1] 8.2.1.2	16.1	X	
– Full load	8.2.1.3 [A1]	16.2	X	
Air removal and steam penetration				
– Bowie and Dick test	[A1] 8.2.2	17	X	X
– Air leakage flow rate	8.2.3	18	X	X
– Air detector, small load	8.2.4.2	19.2	X	X
– Air detector, full load	8.2.4.3	19.3	X	
– Air detector function	8.2.4.4 [A1]	19.4	X	X
[A1] – Hollow load test [A1]	[A1] 8.2.5 [A1]	[A1] 15 [A1]	[A1] X [A1]	
Load dryness tests				
– Small load, textiles	[A1] 8.3.1	20.1	X	
– Full load, textiles	8.3.2	20.2	X	
– Metal load	8.3.3 [A1]	20.3	X	
Sound power	9	21	X	
Dynamic chamber pressure	10	23	X	
Steam quality tests				
– Non-condensable gases	13.3.2	22.1	X	
– Dryness value	13.3.3	22.2	X	
– Superheat	13.3.4	22.3	X	
X = denote a recommended test				

14.2 Calibration

Before carrying out any of the tests the calibration of temperature and pressure instruments shall be checked at the nominal temperature and pressure and that they comply with 6.2.1.3, 6.2.2, 6.3.2.2, 6.3.2.3, 6.3.3.1, 6.3.3.2.

14.3 Environment

The impact on the environment shall be reduced by planning and carrying out the tests in a sequence which will reduce the risk of unnecessary repetition.

NOTE A test sequence could be as follows:

a) safety checks and tests;

b) tests to demonstrate conformity with the specification for each operating cycle;

c) steam quality tests;

d) air leakage test and dynamic pressure test (could be performed simultaneously);

e) thermometric tests, small load;

f) thermometric tests, full load;

g) if more than one sterilization cycle having the same air removal stage is to be tested, it is preferable to carry out initial thermometric tests for those cycles before continuing;

h) Bowie and Dick tests;

i) air detector tests, small load, full load and function;

j) [A1] hollow load test [A1];

k) load dryness tests, full load textiles, small load textiles and metal load;

l) sound power.

15 [A1] Hollow load test

15.1 General

The hollow load test is used to demonstrate that at the levels at which the controls are set, air removal from within the test piece is sufficient to permit even steam penetration into it. The test is performed using the process challenge device unwrapped.

15.2 Apparatus

15.2.1 One hollow load process challenge device as described in EN 867-5, and preconditioned such that the internal environment within the lumen and capsule are at a temperature of between 20 °C and 30 °C and a relative humidity between 40 % and 60 %.

NOTE Residual moisture from previous use, trapped within the hollow load process challenge device will have a deleterious effect on the test results.

15.2.2 Indicator system in accordance with EN 867-5 for the hollow load test.

15.2.3 Connected services complying with Clause 13.

15.3 Procedure

15.3.1 Select the sterilization cycle to be tested (see 7.1.13). Ensure the plateau period is within the time and temperature exposure limits specified for the indicator system identified in 15.2.2.

15.3.2 Carry out a sterilization cycle with the sterilizer chamber empty and without any extended drying time.

NOTE This cycle may be omitted if data is available to demonstrate that conditioning by the previous cycle has a similar effect.

15.3.3 Open the capsule of the hollow load process challenge device and then following the manufacturer's instructions, confirm:

a) liquid water is not visually present;

b) the seal and its mating surfaces are satisfactory.

15.3.4 Following the manufacturer's instructions, insert into the capsule an indicator system (15.2.2) and then close the capsule with the sealing cap.

15.3.5 Place the hollow load process challenge device above the nominal geometric centre of the horizontal plane of the usable space supported between 100 mm and 200 mm above the chamber base.

15.3.6 Carry out a sterilization cycle in accordance with the manufacturers (see 7.1.13) operating procedure.

15.3.7 At the end of the test examine the indicator system for compliance with the requirements specified in 8.2.5.

NOTE For disposal of used indicators attention should be paid to instructions provided by the indicator manufacturer. 〈A1〉

16 Thermometric tests

16.1 Small load, thermometric

16.1.1 General

The small load test, thermometric is used to demonstrate that after the air removal stage of the sterilization cycle sterilizing conditions are obtained within the sterilizer chamber and test pack. The more air there is to remove, the more exacting will be the test; that is why the test pack is used by itself in an otherwise empty sterilizer chamber.

16.1.2 Apparatus

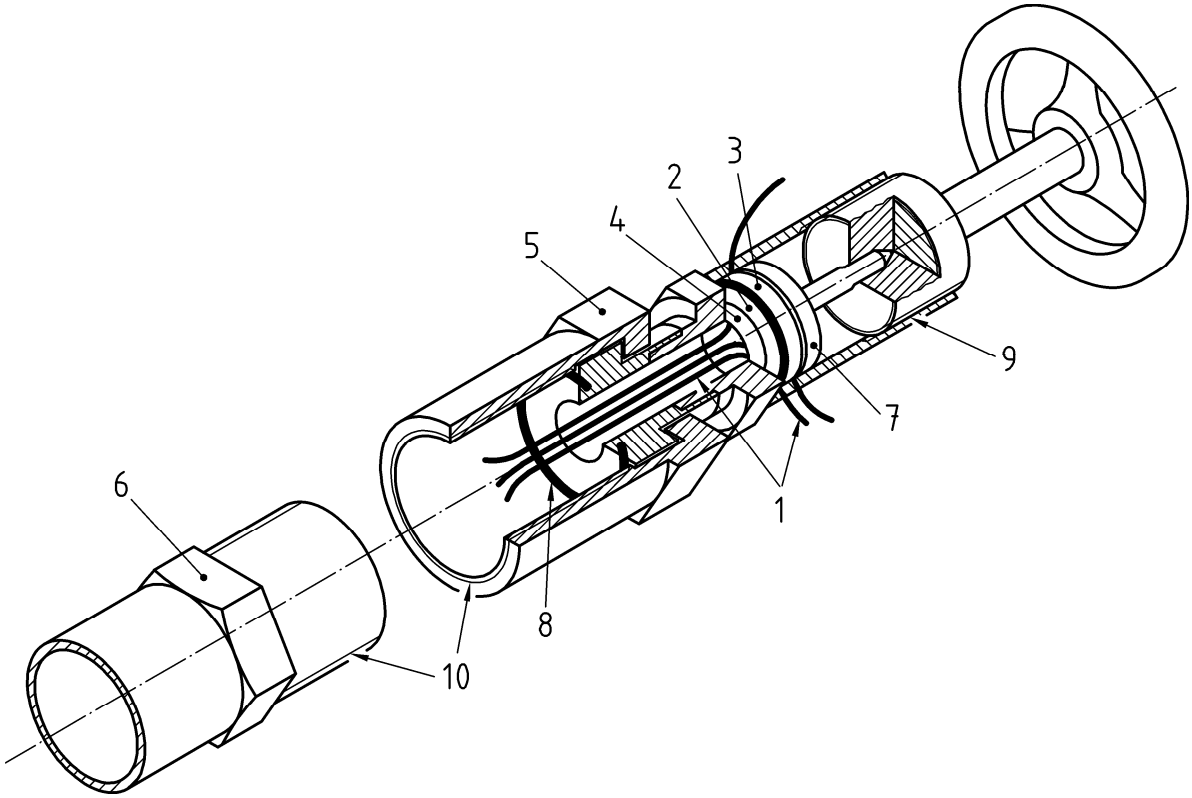
16.1.2.1 Test pack as described in 24.1 for sterilizers exceeding one module and 24.2 for sterilizers of one module.

16.1.2.2 Thermometric and pressure recording instrument as described in 24.5 and 24.6.

16.1.2.3 Seven temperature sensors as described in 24.4.

16.1.2.4 Connection fitting with a pipe thread EN ISO 228-G1 A through which the temperature sensors can be introduced into the sterilizer chamber without affecting its vacuum-tightness and pressure-tightness (see Figure 5).

16.1.2.5 Connected services complying with Clause 13.



Key

1	temperature sensor wire	6	adaptor
2	silicon rubber washer	7	metal thrust spigot
3, 4	metal thrust washer	8	O-ring
5	metal body	9	castellated to permit entry of leads
		10	pipe thread EN ISO 228-G1 A

NOTE 1 Figure 5 shows an example of a fitting which can be used to introduce temperature sensors into a sterilizer chamber. Other methods that guarantee a gas tight seal are equally acceptable.

NOTE 2 If a handle is used either the whole device or the handle should be removed after use.

Figure 5 — Example of a method used to introduce temperature sensors into a sterilizer chamber

16.1.3 Procedure

16.1.3.1 Introduce the temperature sensors into the sterilizer chamber through the temperature sensor entry connection and fitting.

16.1.3.2 Carry out an air leakage test as described in Clause 18. Do not proceed if the air leakage flow rate exceeds that specified in ▌A1⟩ 8.2.3 ⟨A1▐.

16.1.3.3 Place one of the temperature sensors at the reference measurement point.

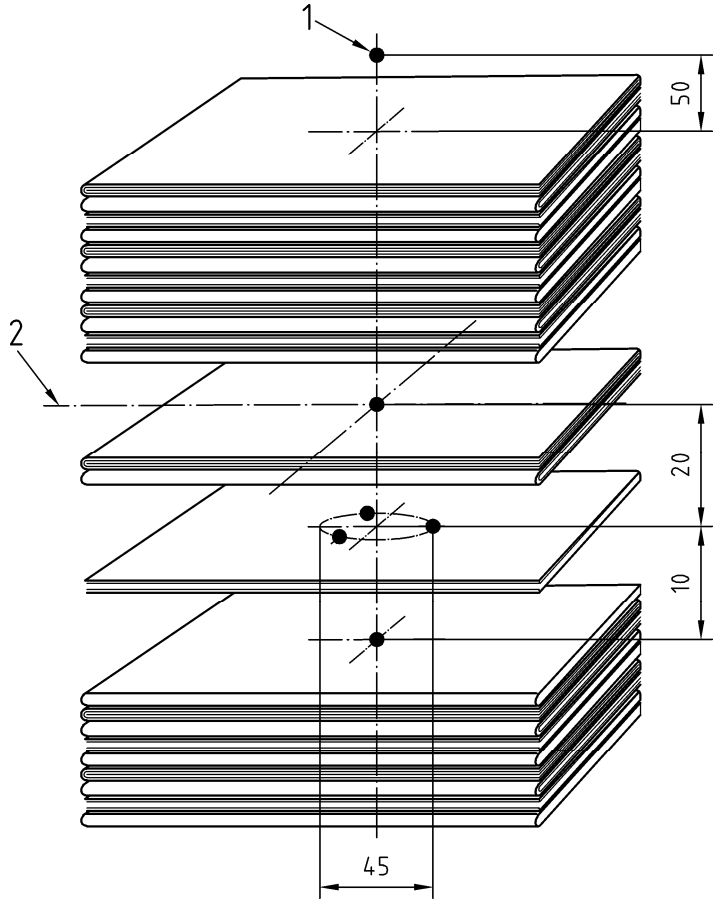
16.1.3.4 Select the sterilization cycle to be tested.

16.1.3.5 Carry out a sterilization cycle with the sterilizer chamber empty.

NOTE The cycle may be omitted if data is available to demonstrate that conditioning by the previous cycle has a similar effect.

16.1.3.6 Remove the wrapping from the test pack and place five temperature sensors within the test pack at locations as indicated in Figure 6. Reassemble and secure as described in 24.1 or 24.2 as appropriate.

Dimensions in millimetres



Key

1 position of sensor

2 centre layer

Figure 6 — Location of temperature sensors

16.1.3.7 Place the test pack above the nominal geometric centre of the horizontal plane of the usable space supported between 100 mm and 200 mm above the chamber base.

For sterilizers of one sterilization module the method shall be modified such that the test pack is supported above the base of the sterilizer chamber.

16.1.3.8 Secure the 7th temperature sensor 50 mm above the upper surface of the test pack and on its nominal vertical centre.

16.1.3.9 Carry out a sterilization cycle and:

— from the independent test records, note the time taken, number of pulses, temperatures, and pressures and levels of vacuum at all significant parts of the sterilization e.g. change from each stage or sub-stage;

— at the beginning, middle and end of the holding time, observe and record the indicated sterilizer chamber temperature and the indicated sterilizer chamber pressure;

— ensure that a recording of the sterilization cycle is made by the recording instrument fitted permanently to the sterilizer (see 6.3).

16.1.3.10 At the completion of the test, proceed as follows:

— check that a visual display of cycle complete is obtained;

— examine the records for compliance with the performance requirements specified in ▌A1⟩ 8.2.1.2 ⟨A1▐;

— examine the records specified above for compliance with the sterilization cycle specification [see 26.3 e)].

16.2 Full load, thermometric

16.2.1 General

The full load test, thermometric is used to demonstrate that at the levels at which the controls are set the required sterilizing conditions will be produced in a test load of specified maximum mass and of sufficient size to fill the usable space.

16.2.2 Apparatus

16.2.2.1 Full load, textiles, as described in 24.7.

16.2.2.2 Thermometric recording and pressure instrument as described in 24.5 and 24.6.

16.2.2.3 Seven temperature sensors as described in 24.4.

16.2.2.4 Connection fitting with a pipe thread EN ISO 228-G1 A through which the temperature sensors can be introduced into the sterilizer chamber without affecting its vacuum-tightness and pressure-tightness (see Figure 5).

16.2.2.5 Connected services complying with Clause 13.

16.2.3 Procedure

16.2.3.1 Introduce the temperature sensors into the sterilizer chamber through the temperature sensor entry connection and fitting.

16.2.3.2 Carry out an air leakage test as described in Clause 18. Do not proceed if the air leakage flow rate exceeds that specified in ▌A1⟩ 8.2.3 ⟨A1▐.

16.2.3.3 Place one of the temperature sensors at the reference measurement point.

16.2.3.4 Select the sterilization cycle to be tested.

16.2.3.5 Carry out a sterilization cycle with the sterilizer chamber empty.

NOTE The cycle may be omitted if data is available to demonstrate that conditioning by the previous cycle has a similar effect.

16.2.3.6 Remove the wrapping from the standard test pack and place five temperature sensors within the test pack at locations as indicated in Figure 6 and one below the top sheet. Reassemble and secure as described in 24.1.

16.2.3.7 Place the standard test pack and stacks of sheets comprising the test sterilizer load into the usable space as described in 24.7.

16.2.3.8 Carry out a sterilization cycle and:

— from the independent test records, note the time taken, number of pulses, temperatures and pressures and levels of vacuum at all significant parts of the sterilization cycle, e.g. change from each stage or sub-stage;

— at the beginning, middle and end of the holding time, observe and record the indicated sterilizer chamber temperature and the indicated sterilizer chamber pressure;

— ensure that a recording of the sterilization cycle is made by the recording instrument fitted permanently to the sterilizer (see 6.3).

16.2.3.9 At the completion of the test, proceed as follows:

— check that a visual display of cycle complete is obtained;

— examine the records and sheets comprising the standard test pack for compliance with the performance requirements specified in [A1] 8.2.1.3 [A1];

— examine the records specified above for compliance with the sterilization cycle specification [see 26.3.e)].

17 Bowie and Dick test

17.1 General

The Bowie and Dick test was conceived as a test for successful air removal for sterilizers so called high vacuum porous load sterilizers. A successful Bowie and Dick test indicates rapid and even penetration of steam into the test pack. Retention of air within the pack due to

— an inefficient air removal stage,

— the presence of an air leak during the air removal stage,

— the presence of non-condensable gases in the steam supply

are circumstances which can lead to failure of the test.

The result of the test can also be affected by other factors which inhibit steam penetration. A failure of the test is therefore not conclusive proof that a fault is due to air retention, air leakage or non-condensable gases and other causes of failure may need to be eliminated.

17.2 Apparatus

17.2.1 Test pack as described in 24.1 for sterilizers exceeding one module and 24.2 for sterilizers of one module.

17.2.2 Indicator in accordance with EN 867-3.

17.2.3 Connected services complying with Clause 13.

17.3 Procedure

17.3.1 Select the sterilization cycle to be tested (see 7.1.13).

17.3.2 Carry out a sterilization cycle with the sterilizer chamber empty and without any extended drying time.

NOTE The cycle may be omitted if data is available to demonstrate that conditioning by the previous cycle has a similar effect.

17.3.3 Remove the wrapping from the test pack and place the indicator in the sheet located in the approximate centre of the test pack. Reassemble and secure as described in 24.1 or 24.2 as appropriate.

17.3.4 Place the test pack above the nominal geometric centre of the horizontal plane of the usable space supported between 100 mm and 200 mm above the chamber base.

For sterilizers of one sterilization module the method shall be modified such that the test pack is supported above the base of the sterilizer chamber.

17.3.5 Carry out a sterilization cycle in accordance with the manufacturer's operating procedure.

17.3.6 At the end of the test examine the indicator for compliance with the requirement specified in ⟨A1⟩ 8.2.2 ⟨A1⟩.

NOTE For disposal of used indicators attention should be paid to instructions provided by the indicator manufacturer.

18 Air leakage test

18.1 General

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 that will inhibit the penetration of steam into the sterilizer load and will not be a potential cause of re-contamination of the sterilizer load during drying.

18.2 Apparatus

18.2.1 Test pressure instrument as described in 24.3.

If the sterilizer is fitted with an absolute pressure instrument complying with 24.3 this additional gauge is not required.

18.2.2 Stopwatch, with an error of not more than ± 0,5 s over a period of 15 min.

18.2.3 Connected services complying with Clause 13.

18.3 Procedure

18.3.1 ⟨A1⟩ Connect the test pressure gauge to the sterilizer chamber with a means to protect it from a pressure of 380 kPa if it is not designed to operate up to 380 kPa. ⟨A1⟩

18.3.2 Stabilize the temperature of the sterilizer chamber (see NOTE) by carrying out one of the following:

— if the pressure vessel incorporates a heated jacket, carry out a sterilization cycle with the sterilizer chamber empty;

— if the pressure vessel does not incorporate a heated jacket, ensure that the temperature of the sterilizer chamber is not more than 20 °C from ambient.

⟨A1⟩ NOTE As an example, in a closed vessel at 4 kPa pressure, the pressure changes by approximately 0,1 kPa for each 10 °C change in temperature, over the range 20 °C to 140 °C; at 7 kPa the change is approximately 0,2 kPa. The test can be compromised if the temperature changes by more than 10 K during the period in which the chamber pressure is monitored. ⟨A1⟩

18.3.3 With the temperature stabilized and the sterilizer chamber empty except for fixed furniture and necessary monitoring sensors, start the test cycle. When the pressure in the sterilizer chamber is 7 kPa ⟨A1⟩ *deleted text* ⟨A1⟩ or below, close all the valves connected to the sterilizer chamber and stop the vacuum pump. Observe and record the time (t_1) and the pressure (p_1). Wait at least 300 s and not more than 600 s to allow evaporation of condensation in the chamber and then observe and record the pressure (p_2) in the sterilizer chamber and the time (t_2). After a further (600 ± 10) s, again observe and record the pressure (p_3) and the time (t_3).

NOTE The sterilizer can be fitted with a test cycle for air leakage which will carry out this procedure automatically and display the air leakage in kilopascals per minute (millibar per minute).

18.3.4 At the end of the test calculate the rate of pressure rise for the 600 s period and check for compliance with [A1] 8.2.3 [A1].

NOTE If the value of (p_2 - p_1) is greater than 2 kPa [A1] *deleted text* [A1], this can be due to the initial presence of excessive condensate in the sterilizer chamber.

19 Air detector tests

19.1 General

An air detector can be fitted to a sterilizer and used to determine whether the non-condensable gases contained in the steam delivered to the sterilizer and the air remaining after the air removal stage of the sterilization cycle are sufficient to cause the sterilizing process to be of uncertain efficacy.

19.2 Air detector, small load

19.2.1 Apparatus

19.2.1.1 Test pack as described in 24.1 for sterilizers exceeding one module and 24.2 for sterilizers of one module.

19.2.1.2 Thermometric recording instrument as described in 24.5.

19.2.1.3 Six temperature sensors as described in 24.4.

19.2.1.4 Connection fitting with a pipe thread EN ISO 228-G1 A through which the temperature sensors can be introduced into the sterilizer chamber without affecting its vacuum-tightness and pressure-tightness (see Figure 5).

19.2.1.5 Metering device as described in [A1] 24.9 [A1].

19.2.1.6 Test pressure instrument as described in 24.3.

If the sterilizer is fitted with an absolute pressure instrument complying with 24.3 this additional gauge is not required.

19.2.1.7 Connected services complying with Clause 13.

19.2.2 Procedure

19.2.2.1 Connect the metering device to the sterilizer chamber using the port provided by the manufacturer.

19.2.2.2 [A1] Connect the test pressure instrument to the sterilizer chamber with a means to protect it from a pressure of 380 kPa if it is not designed to operate up to 380 kPa. [A1]

19.2.2.3 Introduce the temperature sensors into the sterilizer chamber through the temperature sensor entry connection and fitting.

19.2.2.4 Carry out an air leakage test as described in Clause 18. Do not proceed if the air leakage flow rate exceeds that specified in [A1] 8.2.3 [A1].

19.2.2.5 Place one of the temperature sensors at the reference measurement point.

19.2.2.6 Select the sterilization cycle to be tested.

19.2.2.7 Carry out a sterilization cycle with the sterilizer chamber empty.

NOTE The cycle may be omitted if data is available to demonstrate that conditioning by the previous cycle has a similar effect.

19.2.2.8 Remove the wrapping from the test pack and place the temperature sensors within the test pack at locations as indicated in Figure 6. Reassemble and secure as described in 24.1 or 24.2 as appropriate.

19.2.2.9 Place the test pack above the nominal geometric centre of the horizontal plane of the usable space supported between 100 mm and 200 mm above the sterilizer chamber base.

For sterilizers of one sterilization module the method shall be modified such that the test pack is supported above the base of the sterilizer chamber.

19.2.2.10 Carry out a sterilization cycle, but during the air removal stage admit air to the sterilizer chamber by means of the metering device. Control the rate of entry of the air so that, at the start of the plateau period, the lowest temperature measured within the test pack is not more than 2 °C lower than the temperature measured at the reference measurement point.

NOTE It can be necessary to conduct a number of tests in order to establish the air leakage required.

19.2.2.11 Carry out a further air leakage test as described in Clause 18 and then calculate the air leakage flow rate.

19.2.2.12 ▌A1⟩ If the air leakage causes the sterilizer chamber pressure to rise more than 1,1 kPa/min re-adjust the metering device to cause a pressure rise of (1,0 ± 0,1) kPa/min. ⟨A1▐

19.2.2.13 Carry out a sterilization cycle and check that a fault is indicated either during or at the end of the sterilization cycle.

NOTE To facilitate subsequent re-testing, it is advisable to record the setting of the metering device at which the air detector causes a fault to be indicated.

19.3 Air detector, full load

19.3.1 Apparatus

19.3.1.1 Full load, textiles as described in 24.7.

19.3.1.2 Thermometric recording instrument as described in 24.5.

19.3.1.3 Six temperature sensors as described in 24.4.

19.3.1.4 Connection fitting with a pipe thread EN ISO 228-G1 A through which the temperature sensors can be introduced into the sterilizer chamber without affecting its vacuum-tightness and pressure-tightness (see Figure 5).

19.3.1.5 Metering device as described in ▌A1⟩ 24.9 ⟨A1▐.

19.3.1.6 Test pressure instrument as described in 24.3.

If the sterilizer is fitted with an absolute pressure instrument complying with 24.3 this additional gauge is not required.

19.3.1.7 Connected services complying with Clause 13.

19.3.2 Procedure

19.3.2.1 Ensure that the sterilizer complies with the requirements for the air detector test, small load (see ▌A1⟩ 8.2.4.2 ⟨A1▐).

19.3.2.2 Connect the metering device to the sterilizer chamber using the port provided by the manufacturer.

19.3.2.3 [A1] Connect the test pressure instrument to the sterilizer chamber with a means to protect it from a pressure of 380 kPa if it is not designed to operate up to 380 kPa. [A1]

19.3.2.4 Introduce the temperature sensors into the sterilizer chamber through the temperature sensor entry connection and fitting.

19.3.2.5 Carry out an air leakage test as described in Clause 18. Do not proceed if the air leakage flow rate exceeds that specified in [A1] 8.2.3 [A1].

19.3.2.6 Place one of the temperature sensors at the reference measurement point.

19.3.2.7 Select the sterilization cycle to be tested.

19.3.2.8 Carry out a sterilization cycle with the sterilizer chamber empty.

NOTE The cycle may be omitted if data is available to demonstrate that conditioning by the previous cycle has a similar effect.

19.3.2.9 Remove the wrapping from the standard test pack and place the temperature sensors within the standard test pack at locations as indicated in Figure 6. Reassemble and secure as described in 24.1.

19.3.2.10 Place the standard test pack as part of the full load in the sterilizer chamber as described in 24.7.

19.3.2.11 Carry out a sterilization cycle but during the air removal stage admit air to the sterilizer chamber by means of the metering device. Control the rate of entry of air so that, at the start of the plateau period, the temperature measured at the centre of the standard test pack is not more than 2 °C lower than the temperature measured at the reference measurement point.

NOTE It can be necessary to conduct a number of tests in order to establish the air leakage required.

19.3.2.12 Carry out a further air leakage test as described in Clause 18 and then calculate the air leakage flow rate.

19.3.2.13 [A1] If the air leakage causes the sterilizer chamber pressure to rise more than 1,1 kPa/min re-adjust the metering device to cause a pressure rise of (1,0 ± 0,1) kPa/min. [A1]

19.3.2.14 Carry out a sterilization cycle and check that the air detector causes a fault to be indicated either during or at the end of the test cycle.

NOTE To facilitate subsequent re-testing it is advisable to record the setting of the metering device at which the air detector causes a fault to be indicated.

19.4 Air detector function

19.4.1 General

The air detector function test is used to provide assurance that the setting of the air detector remains valid.

19.4.2 Apparatus

19.4.2.1 Test pack as described in 24.1 for sterilizers exceeding one module and 24.2 for sterilizers of one module.

19.4.2.2 Metering device as described in [A1] 24.9 [A1].

19.4.2.3 Connected services complying with Clause 13.

19.4.3 Procedure

19.4.3.1 Connect the metering device to the sterilizer chamber using the port provided by the manufacturer.

19.4.3.2 Carry out an air leakage test as described in Clause 18. Do not proceed if the air leakage flow rate exceeds that specified in [A1] 8.2.3 [A1].

19.4.3.3 Select the sterilization cycle to be tested.

19.4.3.4 Carry out a sterilization cycle with the sterilizer chamber empty.

NOTE The cycle may be omitted if data is available to demonstrate that conditioning by the previous cycle has a similar effect.

19.4.3.5 Open the valve on the port designated by the manufacturer.

19.4.3.6 Set the metering device to the setting determined during the air detector test, small load (see 19.2).

19.4.3.7 Place the test pack above the nominal geometric centre of the horizontal plane of the usable space supported between 100 mm and 200 mm above the sterilizer chamber base.

For sterilizers of one sterilization module the method shall be modified such that the test pack is supported above the base of the sterilizer chamber.

19.4.3.8 Carry out a sterilization cycle.

19.4.3.9 At the end of the sterilization cycle check for compliance with the requirement specified in [A1] 8.2.4.4 [A1].

19.4.3.10 Close the valve on the port designated by the manufacturer.

20 Load dryness tests

20.1 Load dryness, small load, textiles

20.1.1 General

The load dryness test, small load, textiles, is used to demonstrate that the sterilization cycle without extended drying will not cause an increase in moisture in a test pack sufficient to cause uncertainty in the dryness of sterilizer loads routinely sterilized.

20.1.2 Apparatus

20.1.2.1 Test pack as described in 24.1 for sterilizers exceeding one module and 24.2 for sterilizers of one module.

20.1.2.2 Balance, capable of weighing a load of at least 8 kg and with an accuracy of at least ± 1 g.

20.1.2.3 Stop watch.

20.1.2.4 Connected services complying with Clause 13.

20.1.3 Procedure

20.1.3.1 Allow the sheets of the test pack to equilibrate as described in 24.1 or 24.2 as appropriate.

20.1.3.2 Weigh the test pack (m_1).

20.1.3.3 Select the sterilization cycle to be tested.

20.1.3.4 Carry out the cycle to be tested with the sterilizer chamber empty.

NOTE The cycle may be omitted if data is available to demonstrate that conditioning by the previous cycle has a similar effect.

20.1.3.5 Place the test pack above the nominal geometric centre of the horizontal plane of the usable space supported between 100 mm and 200 mm above the chamber base.

For sterilizers of one sterilization module the method shall be modified such that the test pack is supported above the base of the sterilizer chamber.

20.1.3.6 Carry out a sterilization cycle. Start the sterilization cycle within 60 s of placing the test pack in the sterilizer chamber.

20.1.3.7 Within 120 s after completion of the sterilization weigh the test pack (m_2). Record the result.

20.1.3.8 Calculate the change in moisture content (in per cent) of the test pack using the Equation (2):

$$\Delta m = \frac{(m_2 - m_1)}{(m_1)} \times 100 \ \% \qquad (2)$$

where

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

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

m_2 is the mass of the test pack after sterilization, in grams;

20.1.3.9 Check that the result complies with ▌A1⟩ 8.3.1 ⟨A1▐.

20.2 Load dryness, full load, textiles

20.2.1 General

The load dryness test, full load, textiles, is used to demonstrate that the sterilization cycle will not cause an unacceptable level of moisture to be absorbed by a standard test pack located in a full load of textiles.

20.2.2 Apparatus

20.2.2.1 Full load, textiles as described in 24.7.

20.2.2.2 Balance, capable of weighing a load of at least 8 kg and with an accuracy of at least ± 1 g.

20.2.2.3 Stop watch.

20.2.2.4 Connected services complying with Clause 13.

20.2.3 Procedure

20.2.3.1 Allow the sheets of the standard test pack to equilibrate as described in 24.1.

20.2.3.2 Weigh the standard test pack (m_1).

20.2.3.3 Select the sterilization cycle to be tested.

20.2.3.4 Carry out a sterilization cycle with the sterilizer chamber empty.

NOTE The cycle may be omitted if data is available to demonstrate that conditioning by the previous cycle has a similar effect.

20.2.3.5 Place the test load in the sterilizer chamber as described in 24.7.

20.2.3.6 Carry out a sterilization cycle. Start the sterilization cycle within 60 s of placing the test load in the sterilizer chamber.

20.2.3.7 Within 120 s after completion of the sterilization weigh the standard test pack (m_2). Record the result.

20.2.3.8 Calculate the change in moisture content (in per cent) of the standard test pack using the Equation (2) in 20.1.3.8.

20.2.3.9 Check that the result complies with ▌A1⟩ 8.3.2 ⟨A1▐.

20.3 Load dryness, metal load

20.3.1 General

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

If moisture problems are identified after the test has been successfully completed the cause can be the type of load and its location in the sterilizer chamber.

20.3.2 Apparatus

20.3.2.1 Test pack, metal as described in ▌A1⟩ 24.8 ⟨A1▐.

20.3.2.2 Balance, capable of weighing a load of at least 15 kg and with an accuracy of at least ± 1 g.

20.3.2.3 Stop watch.

20.3.2.4 Connected services complying with Clause 13.

20.3.3 Procedure

20.3.3.1 All items used to form the test pack shall be equilibrated in accordance with ▌A1⟩ 24.8 ⟨A1▐.

20.3.3.2 Weigh the test pack, metal, and record its mass (m_1).

20.3.3.3 Select the sterilization cycle to be tested.

20.3.3.4 Carry out a sterilization cycle with the sterilizer chamber empty.

NOTE The cycle may be omitted if data is available to demonstrate that conditioning by the previous cycle has a similar effect.

20.3.3.5 Place the test pack, metal, in the usable space, on the lower shelf.

20.3.3.6 Fill the remaining usable space with self-draining steel objects to give a total mass of 15 kg in each sterilization module.

These items shall be equilibrated to ambient conditions.

20.3.3.7 Check that the temperature in the test pack is within (25 ± 2) °C and start a sterilization cycle within 60 s.

20.3.3.8 At the completion of the sterilization cycle remove the test pack, metal, from the sterilizer chamber and weigh within a total period of 5 min. Record its mass (m_2).

20.3.3.9 Calculate the change in moisture content (in per cent) using the Equation (3):

$$\Delta m = \frac{m_2 - m_1}{m_1} \times 100 \ \% \qquad (3)$$

where

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

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

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

20.3.3.10 Check that the result complies with ▌A1⟩ 8.3.3 ⟨A1▐.

21 Sound power test

21.1 Apparatus

21.1.1 A sound level meter, complying with Type 1 of EN 61672-1:2003 or an integrating averaging sound level meter complying with Type 1 of EN 61672-2:2003.

21.1.2 Test room, with a sound reflecting floor (e.g. tiles, concrete).

21.1.3 Full load, textiles, as described in 24.7.

21.2 Procedure

21.2.1 Locate the microphones in the position described in EN ISO 3746:1995, 7.3.

NOTE 1 The reference surface is the smallest rectangular parallelepiped (box) that just encloses the sterilizer. It is a box formed by the structure and coverings or, where these are not fitted, it is a box having a width and depth measured from the outside of the vessel lagging and a height measured from the floor to the top of the vessel lagging.

NOTE 2 The reference surface does not include pipes and valves used to connect the sterilizer to its services.

21.2.2 Determine the correction factors K_{1A} and K_{2A} as described in EN ISO 3746:1995, Clause 8. Before proceeding, confirm that the values are valid when used to determine the weighted sound power and impulsive noise index according to EN ISO 3746:1995.

21.2.3 With the sterilizer containing the test load carry out the test, ensuring that the pressure and flow from the steam and water services are set to levels which cause the maximum noise and are within the ranges specified for the sterilizer.

NOTE When the sterilizer is designed for a number of sterilization cycles, the textile cycle employing the highest temperature should be selected.

21.2.4 Using the procedure for measurements on a rectangular measurement surface described in EN ISO 3746:1995, 7.3 determine the A-weighted sound power level (L_{WA}) of the sterilizer for one complete sterilization cycle.

NOTE The sound power level is determined from a number of sensor positions. If the sound meter has insufficient input channels, additional instruments and/or repeated sterilization cycles are performed.

21.2.5 Identify the microphone in the noisiest location and then determine as described in EN ISO 3746:1995, Annex D the maximum impulsive noise index for a 1 s interval occurring during a complete sterilization cycle.

21.3 Test result

Record the calculated A-weighted sound power level in decibels to the nearest integer and the maximum impulsive noise index also to the nearest integer.

22 Steam quality tests

22.1 Non-condensable gases

22.1.1 General

The steam quality test, non-condensable gases, is used to demonstrate that the level of non-condensable gases contained in the steam will not prevent the attainment of sterilization conditions in any part of the sterilizer load. The test method described should be regarded not as measuring the exact level of non-condensable gases during normal use of the sterilizer but a method to evaluate compliance with the requirement in 13.3.2. The concentration of non-condensable gases changes considerably. A peak which occurs for a few seconds can be sufficient to cause a fault during sterilization.

An alternative procedure to the one described in 22.1 can be used providing it has been calibrated against this European Standard.

22.1.2 Apparatus

22.1.2.1 Burette, of 50 ml (nominal) capacity having a minimum scale mark of 1 ml.

22.1.2.2 Funnel, with parallel sides and with a major diameter of approximately 50 mm.

22.1.2.3 Container of 2 000 ml (nominal) capacity and with an overflow pipe to limit the contained capacity to approximately 1 500 ml.

22.1.2.4 Sampling pipe, "U" shaped, made from 6 mm (nominal) outside diameter glass tubing and with a 75 mm (nominal) delivery limb.

22.1.2.5 Small needle valve, having a 1 mm (nominal) orifice and with suitable fittings for connection to the steam pipe and rubber sampling tube.

22.1.2.6 Graduated cylinder of 250 ml (nominal) capacity and having minimum scale mark of 10 ml.

22.1.2.7 Burette stand.

22.1.2.8 Rubber tubing (950 ± 50) mm long, self-draining and having a bore suitable for connection to the sampling pipe and needle valve.

NOTE Silicone tubing is permeable to air and therefore should not be used.

22.1.2.9 Temperature measurement system with an accuracy of at least 1 °C at 80 °C.

22.1.3 Procedure

22.1.3.1 Connect the needle valve to the steam pipe as shown in Figure 7.

22.1.3.2 Assemble the apparatus as shown in Figure 7 and then locate it in a position, which will allow the free drainage of condensate through the rubber tubing.

22.1.3.3 Fill the container with cold de-aerated water, (water which has been boiled for 5 min and then cooled), until it flows through the overflow pipe.

22.1.3.4 Fill the burette with cold de-aerated water, invert it and place it in the container ensuring that no air is introduced into the burette.

22.1.3.5 With the steam sampling pipe out of the container open the needle valve and purge all air from the pipe. Place the sampling pipe in the container and add more cold de-aerated water until it flows through the overflow pipe.

22.1.3.6 Position the graduated cylinder under the container overflow and locate the steam sampling pipe within the funnel. Adjust the needle valve to allow a continuous sample of steam into the funnel sufficient to cause a small amount of "steam hammer" to be heard. Ensure that the steam entering the funnel is discharged so that the non-condensable gases are collected in the burette.

22.1.3.7 Close the needle valve, after first noting the "open" position.

22.1.3.8 Start a sterilization cycle and ensure that the graduated cylinder is empty and the container is filled with water. When the steam supply to the sterilizer chamber commences, re-open the needle valve to allow a continuous sample of steam into the funnel sufficient to cause a small amount of "steam hammer" to be heard.

22.1.3.9 Allow the steam sample to condense in the funnel and the non-condensable gases to rise to the top of the burette. Collect the overspill formed by the condensate and the water displaced by the gases in the graduated cylinder. Close the needle valve when the temperature of the water in the container is between 70 °C and 75 °C. Record the volume (V_b) of water displaced from the burette and the volume (V_c) of water collected in the graduated cylinder.

NOTE A sequence of tests should be undertaken to determine whether the level of non-condensable gases in the steam is variable.

22.1.3.10 Calculate the concentration of non-condensable gases as a percentage using Equation (4):

$$C_n = \frac{V_b}{V_c} \times 100 \ \% \qquad (4)$$

where

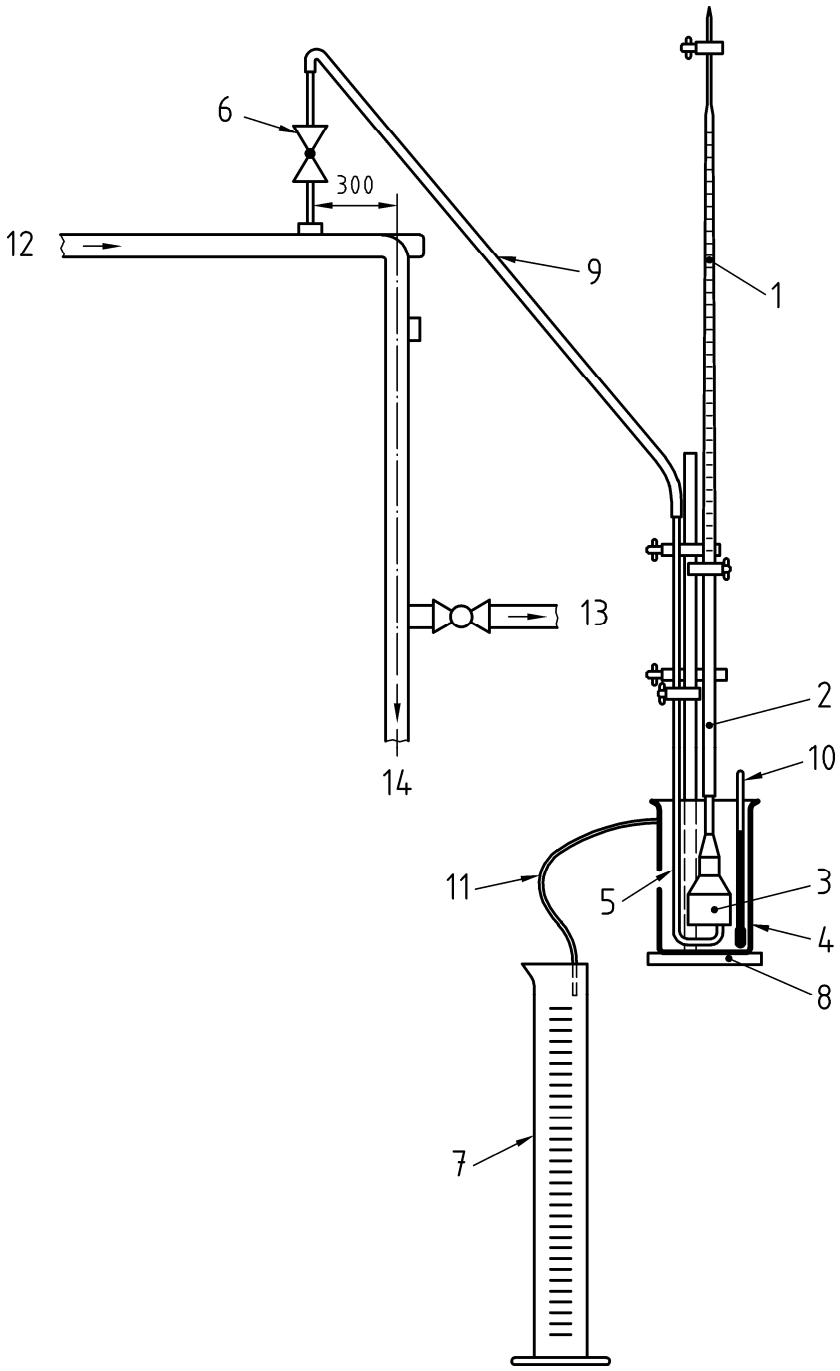
C_n is the concentration of non-condensable gases, in per cent;

V_b is the volume of water displaced from the burette, in millilitres;

V_c is the volume of water collected in the graduated cylinder, in millilitres.

22.1.3.11 Check that the result complies with the requirements specified in 13.3.2.

Dimensions in millimetres



Key

1	50 ml burette	6	needle valve	12	from steam service
2,9	rubber tubing	7	250 ml measuring cylinder	13	to sterilizer
3	funnel with parallel sides	8	burette stand	14	to trap set
4	2 000 ml container	10	temperature measurement system		
5	steam sampling pipe	11	overflow pipe		

Figure 7 — Diagrammatic representation of the apparatus for the measurement of non-condensable gases

22.2 Dryness

22.2.1 General

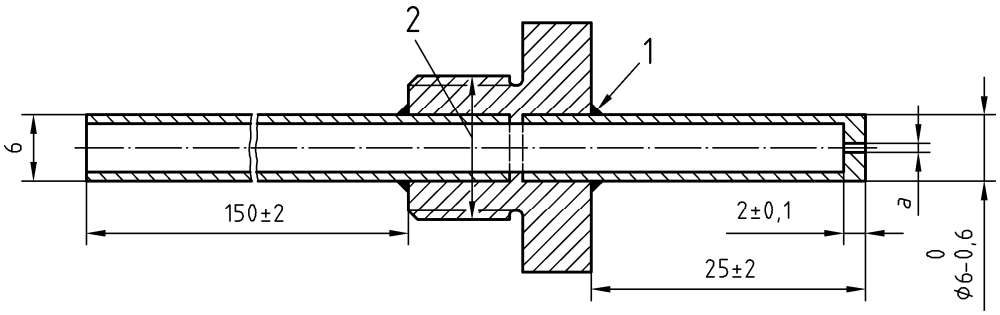
A continuous supply of saturated steam is required for steam sterilization. Excess moisture carried in suspension can cause damp loads, while too little can not prevent the steam from becoming superheated during expansion into the sterilizer chamber. The accurate measurement of the percentage of moisture content in the steam is difficult and the traditional methods where constant steam flow is required are not suitable for sterilizers. The test method described should be regarded not as measuring the true content of moisture in the steam, but as a method by which the provision of acceptable steam quality can be demonstrated.

An alternative procedure to the one described in 22.2 can be used providing it has been calibrated against this European Standard.

22.2.2 Apparatus

22.2.2.1 Pitot tube constructed as shown in Figure 8 and fitted with a sensing tube having a bore to suit the pressure in the steam pipe from which the sample is to be taken.

Dimensions in millimetres



Steam pressure kPa (bar)	Bore a mm ± 0,02
up to 300 (2)	0,8
up to 400 (3)	0,6
up to 700 (6)	0,4

Key

1 silver solder

2 pipe thread EN ISO 228-G1/4 A

NOTE The values given in the table are for guidance only. When the steam pressure is not within the ranges given, the bore 'a' size can be determined by extrapolation.

Figure 8 — Pitot tube

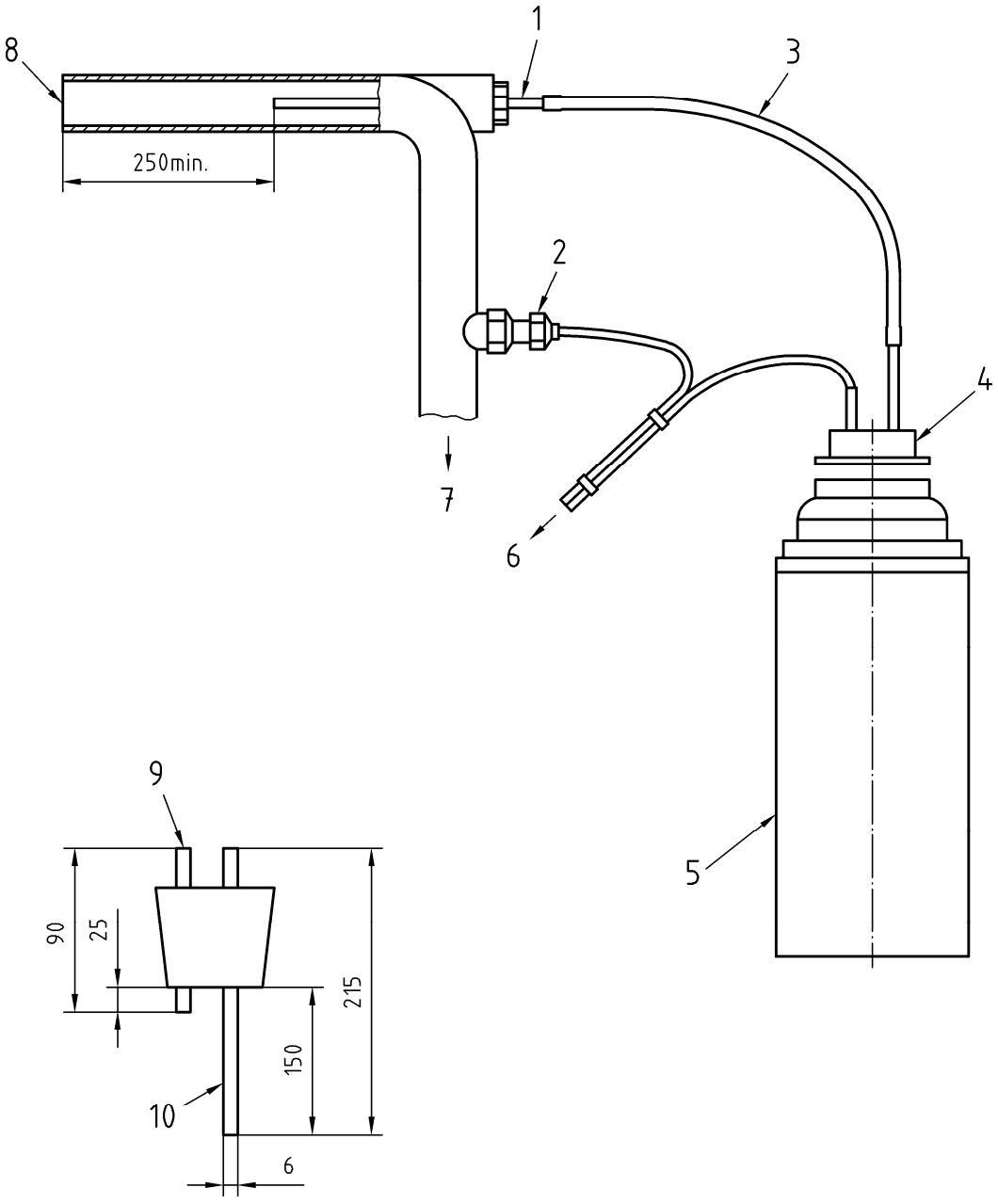
22.2.2.2 Dewar flask of 1 l nominal capacity.

22.2.2.3 Gland for inserting a temperature sensor into the steam pipe.

22.2.2.4 Thermometric recording instrument as described in 24.5 but having a scale range which includes 0 °C to 200 °C.

22.2.2.5 Two temperature sensors as described in 24.4.

Dimensions in millimetres



Key

1	pitot tube	6	to temperature measuring instrument
2	temperature sensor entry gland	7	to sterilizer
3	rubber tubing	8	from steam service
4	rubber bung assembly	9	pipe for thermocouple and vent
5	one-litre Dewar flask	10	sample pipe

Figure 9 — Diagrammatic representation of the apparatus for the measurement of steam dryness value

22.2.2.6 Rubber stopper, fitted with two 6 mm (nominal) outside diameter pipes for insertion into the Dewar flask. Nominal lengths of insertion of the pipes 25 mm and 150 mm respectively.

NOTE Silicone stopper is permeable to air and therefore should not be used.

22.2.2.7 Rubber tubing, self-draining, having a length of (450 ± 50) mm and a bore suitable for connection to the pitot tube and the longer of the tubes in the rubber stopper.

NOTE Silicone tubing is permeable to air and therefore should not be used.

22.2.2.8 Balance, capable of weighing a load of at least 2 kg and with an accuracy of at least ± 0,1 g.

22.2.2.9 Standard test pack as described in 24.1.

22.2.3 Procedure

22.2.3.1 Carry out a steam quality test for non condensable gases in accordance with 22.1. If the values are not within the limits specified in 13.3.2 the fault shall be corrected before carrying out this test.

22.2.3.2 Fit the pitot tube concentrically within the steam service pipe as shown in Figure 9.

22.2.3.3 Fit the temperature sensor entry gland to the steam service pipe and locate one of the temperature sensors at the nominal axial centre of the pipe.

22.2.3.4 Connect the rubber tube to the longer of the pipes in the stopper and then place the stopper in the neck of the Dewar flask, weigh the whole assembly and record the mass (m_e).

22.2.3.5 Where the sterilizer has a number of sterilization cycles select the textile cycle with a sterilization temperature of 134 °C.

22.2.3.6 Carry out a sterilization cycle with the sterilizer chamber empty.

22.2.3.7 Remove the stopper and tube assembly and place (650 ± 50) ml of water at a temperature not exceeding 27 °C into the Dewar flask. Replace the stopper and tube assembly, weigh the whole assembly and record the mass (m_s).

22.2.3.8 Support the Dewar flask close to the pitot tube connection point and in a position which is protected from excess heat and draughts.

22.2.3.9 Place the standard test pack as described in 24.1 in the sterilizer chamber.

22.2.3.10 Introduce the second temperature sensor through the shorter of the pipes in the stopper and into the Dewar flask.

22.2.3.11 Note the temperature of the fluid in the Dewar flask (T_1).

22.2.3.12 Carry out a sterilization cycle. When the steam valve connected to the sterilizer chamber first opens attach the rubber tube to the pitot tube connection point ensuring free drainage of condensate into the Dewar flask.

22.2.3.13 Note the temperature of the steam (T_3).

22.2.3.14 When the temperature of the water in the Dewar flask is approximately 80 °C, disconnect the rubber tube from the pitot tube connection; agitate the flask so that the contents are thoroughly mixed and then note the temperature of the fluid (T_2).

22.2.3.15 Weigh the Dewar flask complete with water, condensate, stopper and tube (m_f).

22.2.3.16 Calculate the dryness value of the steam from the following equation:

$$D = \frac{(T_2 - T_1)(c_{pw}(m_s - m_e) + A)}{L(m_f - m_s)} - \frac{(T_3 - T_2)\,cpw}{L} \quad (5)$$

where

L is the latent heat of saturated steam at temperature T_3, in kilojoules per kilogram;

m_e is the mass of the Dewar flask and stopper, pipes and tube, in kilograms;

m_s is the mass of the Dewar flask, water charge stopper pipes and tube, in kilograms;

m_f is the mass of the flask, water charge, condensate, stopper, pipes and tube, in kilograms;

T_1 is the initial temperature of the water in the Dewar flask, in degrees Celsius;

T_2 is the final temperature of the water, and condensate in the Dewar flask, in degrees Celsius;

T_3 is the temperature of saturated steam delivered to the sterilizer, in degrees Celsius;

c_{pw} is the specific heat capacity of water (4,18 kJ/kg · K);

D is the dryness value of the steam;

A is the effective heat capacity of the apparatus (0,24 kJ/K).

22.2.3.17 Check that the result complies with 13.3.3.

22.3 Superheat

22.3.1 General

The steam quality test, superheat is used to demonstrate that the amount of moisture in suspension with steam supplied from the service supply is sufficient to prevent the steam from becoming superheated during expansion into the sterilizer chamber. The test method described in 22.3 uses a low volume sample, continuously taken from the centre of the steam service pipe. The level of super heat determined by this method cannot be regarded as the true dryness of the steam in the pipe since condensate flowing along the inside surface is not collected. However, devices designed to separate free condensate are incorporated into the steam delivery system to the sterilizer chamber and therefore the level determined by this method is representative of steam conditions likely to prevail within the sterilizer chamber during the plateau period.

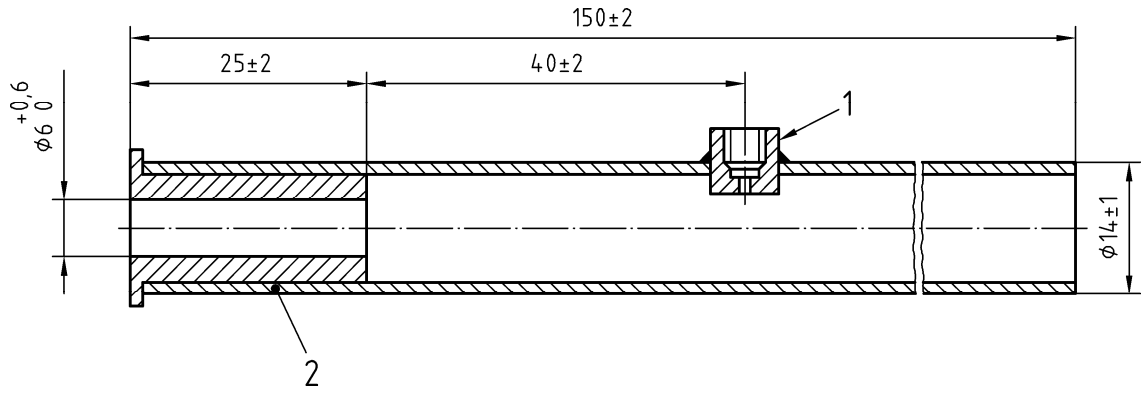
An alternative procedure to the one described in 22.3 can be used providing it has been correlated to this method.

22.3.2 Apparatus

22.3.2.1 Pitot constructed as shown in Figure 8 and having a nominal bore of 1 mm.

22.3.2.2 Expansion tube as shown in Figure 10.

Dimensions in millimetres



Key

1 suitable fitting for locating a temperature sensor into the tube

2 nylon socket, fit into the tube

Figure 10 — Expansion tube

22.3.2.3 150 mm (nominal) length of 15 mm pipe lagging.

22.3.2.4 Thermometric recording instrument as described in 24.5.

22.3.2.5 Two temperature sensors as described in 24.4.

22.3.2.6 Gland for inserting a temperature sensor into the steam pipe.

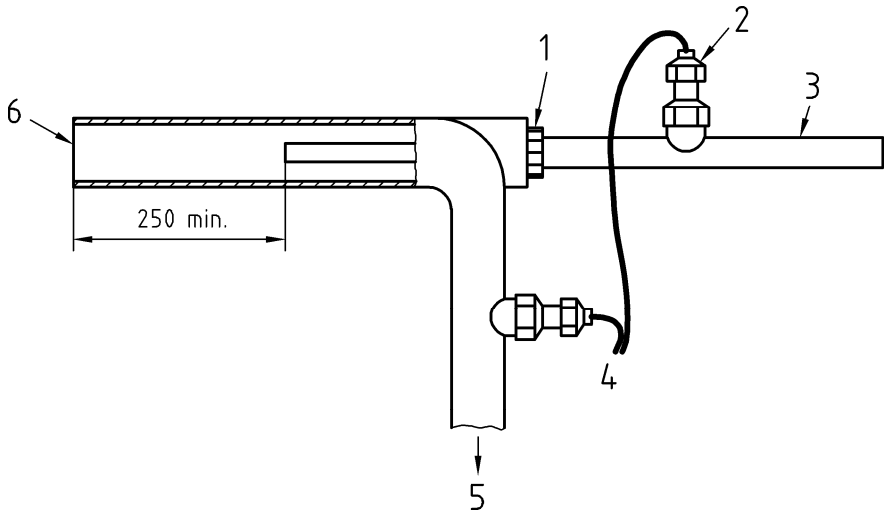
NOTE To reduce heat transfer between the fitting and temperature sensor, insulation can be required.

22.3.2.7 Full load, textiles as described in 24.7.

22.3.3 Procedure

22.3.3.1 Fit the pitot tube concentrically within the steam service pipe as shown in Figure 11.

Dimensions in millimetres



Key

1	pitot tube	4	to temperature measuring instrument
2	temperature sensor fitting	5	to sterilizer
3	expansion tube	6	from steam service

Figure 11 — Diagrammatic representation of the apparatus for the measurement of superheat

22.3.3.2 Fit the temperature sensor entry gland to the steam pipe and locate one of the temperature sensors at the nominal axial centre, as shown in Figure 9.

22.3.3.3 Through the gland provided, locate the second temperature sensor at the approximate horizontal axis of the expansion tube.

22.3.3.4 Attach the pipe lagging around the expansion tube and push the expansion tube on to the pitot.

22.3.3.5 Connect the temperature sensors to the thermometric recording instrument.

22.3.3.6 Carry out a sterilization cycle with the sterilizer chamber empty.

22.3.3.7 Place the full load, textiles in the usable space as described in 24.7 and within 5 min carry out a further sterilization cycle.

22.3.3.8 At the end of the sterilization cycle check the temperature recordings

— for compliance with the requirement specified in 13.3.4,

— to confirm that the temperature measured in the steam pipe did not differ by more than 3 °C from that measured in the steam pipe during the steam quality, dryness test.

NOTE This temperature is a parameter from which the variability of the steam pressure between sequential cycles can be assessed. A higher temperature difference can cause operational problems from the moisture content in the steam.

22.4 Procedure for sampling steam condensate

22.4.1 Apparatus

22.4.1.1 Pitot tube constructed as shown in Figure 8 and fitted with an orifice having a nominal bore to suit the pressure in the steam service pipe from which the sample is to be taken.

22.4.1.2 Polypropylene tube (5 000 ± 50) mm long and having a bore (6 ± 1) mm.

22.4.1.3 Two graduated polypropylene bottles, each having a nominal capacity of 250 ml.

22.4.1.4 Container with a minimum capacity of 8 l.

22.4.1.5 Approximately 1 kg of ice.

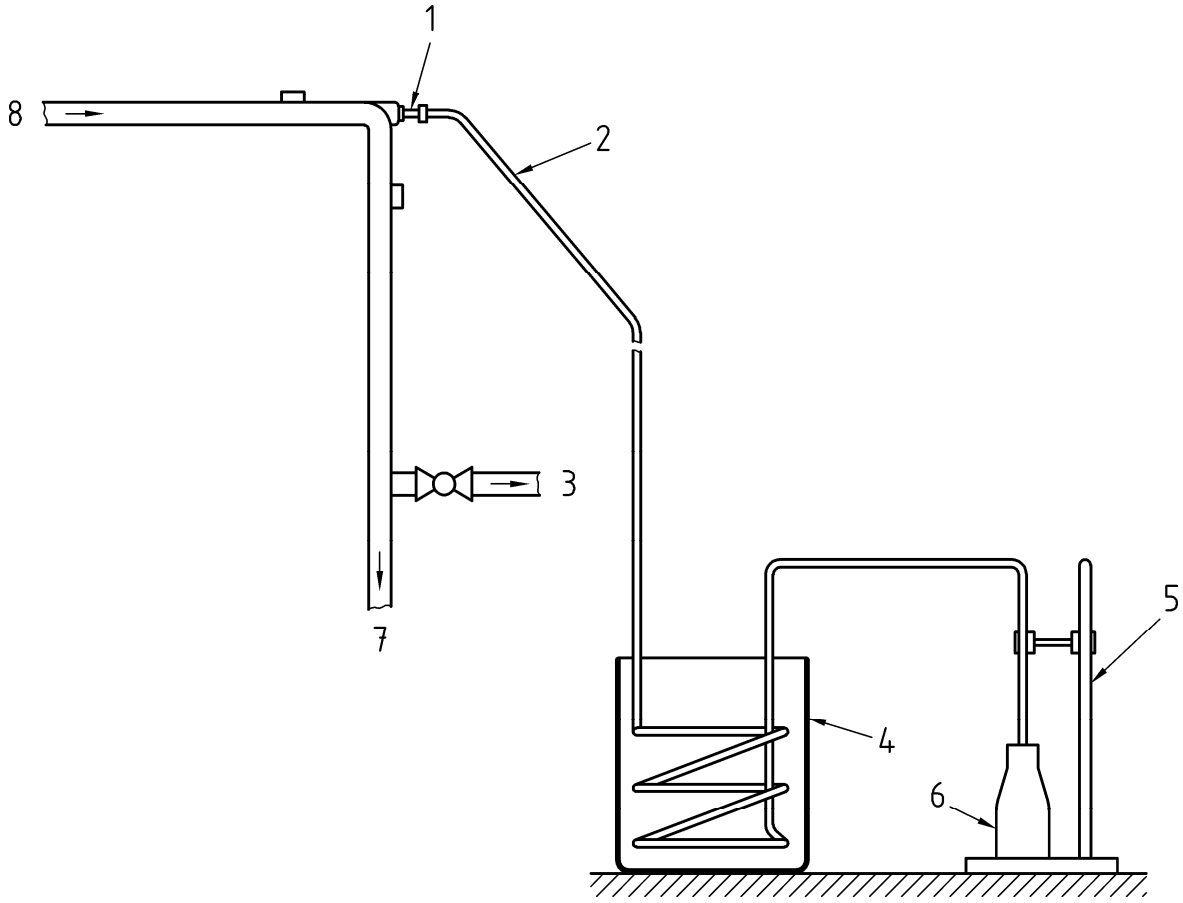
22.4.1.6 A clip or connector which can be used to secure the polypropylene tube to the pitot.

22.4.1.7 A piece of metal of a mass and size suitable for retaining a number of coils of the polypropylene tube in the container.

22.4.1.8 Small volume of concentrated hydrochloric acid.

22.4.2 Procedure

22.4.2.1 Fit the pitot tube into the steam service pipe as shown in Figures 9 and 12.



Key

1	pitot tube	5	burette stand
2	polypropylene tube, coiled as shown	6	250 ml polypropylene bottle
3	to sterilizer	7	to trap set
4	8 000 ml container	8	from steam service

Figure 12 — Apparatus for sampling steam condensate

22.4.2.2 Using the clip, secure the polypropylene tube to the pitot connection.

22.4.2.3 Open the valve on the steam service pipe and discharge steam condensate through the polypropylene tube for a minimum period of 5 min. Ensure the condensate drains freely.

22.4.2.4 Clean and rinse both the inside of the polypropylene tube and the two bottles with distilled water and then dry them. Close the steam valve.

22.4.2.5 Arrange the burette and one of the bottles as shown in Figure 12.

22.4.2.6 Coil part of the polypropylene tubing into sufficient number of coils to ensure condensation of steam, place in the container and retain by the metal weight.

22.4.2.7 Fill the container with the ice and sufficient quantity of cold water to immerse the tubing.

22.4.2.8 Open the steam service valve.

22.4.2.9 Allow at least 50 ml of steam condensate to discharge to waste and then collect 250 ml (nominal) in the first graduated bottle.

22.4.2.10 Seal this polypropylene bottle.

22.4.2.11 Collect 250 ml of condensate and add sufficient concentrated hydrochloric acid to the second polypropylene bottle to give a final concentration of c_{HCl} = 0,1 mol/l and seal the bottle. Mark the bottle "for trace metal analysis".

23 Dynamic sterilizer chamber pressure test

23.1 General

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 can cause damage to the package. This level is used as a performance requirement for packaging materials complying with EN 868 and has been chosen on the basis of a compromise between the need to provide cost effective packaging and short efficacious sterilization cycles.

23.2 Apparatus

23.2.1 Pressure recording instrument as described in 24.6.

23.3 Procedure

23.3.1 Attach the pressure recording instrument to the test connection (see 4.3.3.2) using the prescribed connecting tube (see 24.6.8).

23.3.2 Carry out an air leakage test as described in Clause 18. Do not proceed if the air leakage flow rate exceeds that specified in [A1] 8.2.3 [A1].

23.3.3 Select the sterilization cycle to be tested.

23.3.4 Carry out a sterilization cycle with the sterilizer chamber empty and observe and record the times, temperatures and pressures at all significant parts of the sterilization cycle.

23.3.5 At the completion of the test, proceed as follows:

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

— check that the pressure difference for any interval of 3 s complies with Clause 10.

24 Test apparatus, equipment and material

24.1 Standard test pack

24.1.1 This test pack is used to check that, at the levels at which the process variables are set, rapid and even penetration of steam into the pack is attained.

It is used for the Bowie and Dick test, the small load test, air detector tests, load dryness test, textiles and can be used with other materials to form a full load.

The standard test pack is a reusable item that may be used for testing continuously if the requirements in 24.1.3 and 24.1.4 are met. The environmental aspects regarding cleaning intervals as well as means for cleaning and conditioning should be considered.

24.1.2 The test pack shall be composed of plain cotton sheets, each bleached to a good white and having an approximate size of 900 mm x 1 200 mm. The number of threads per centimetre in the warp shall be (30 ± 6) and the number of threads per centimetre in the weft (27 ± 5), the weight shall be (185 ± 5) g/m², the edges, which are no self-edges shall not be hemmed.

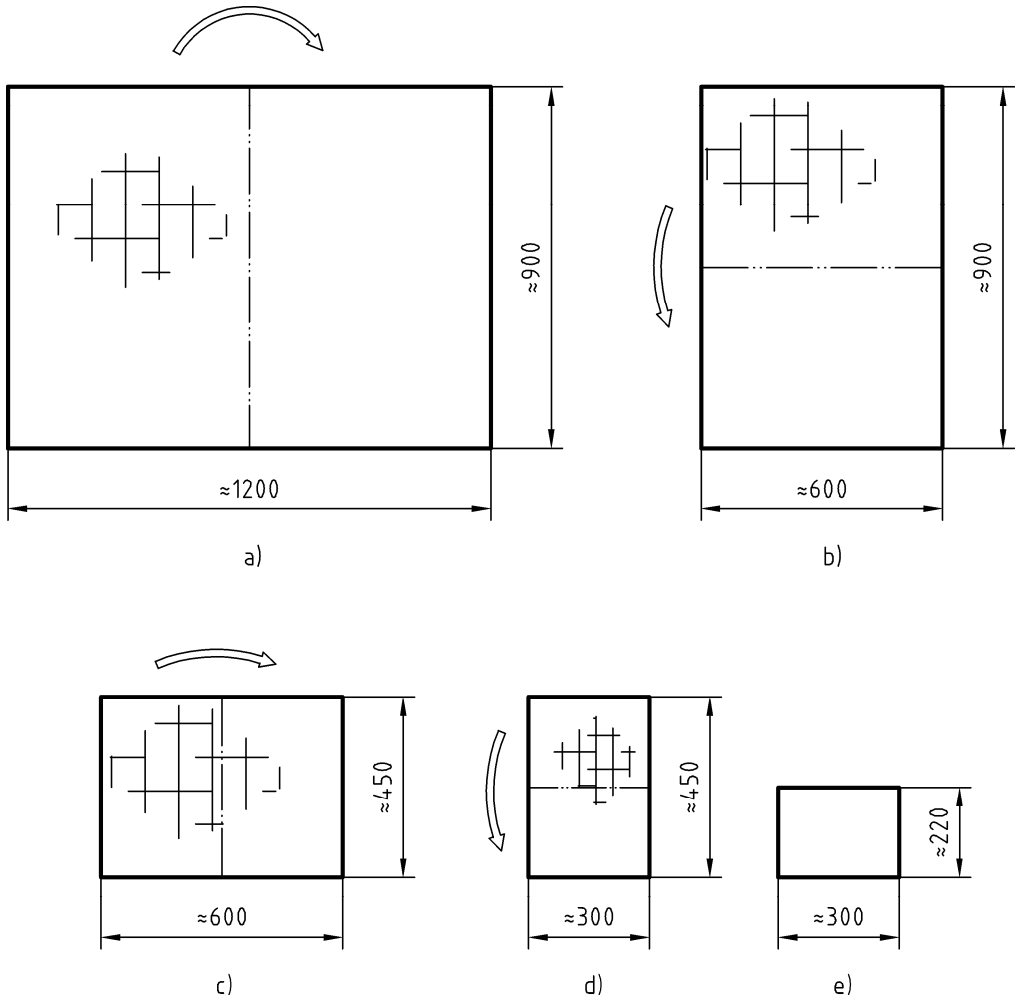
24.1.3 The sheets shall be washed when new or soiled and shall not be subjected to any fabric conditioning agent during laundering.

NOTE Fabric conditioning agents can affect the characteristics of the fabric and can contain volatiles which will contribute to the non-condensable gases in the sterilizer.

24.1.4 The sheets shall be dried and then allowed to equilibrate in an environment of between 20 °C to 30 °C and a relative humidity of 40 % to 60 %.

24.1.5 The test pack shall be folded and assembled in accordance with Figure 13.

Dimensions in millimetres



Key
a) 1 layer, unfolded
b) 2 layers, 1-times folded
c) 4 layers, 2-times folded
d) 8 layers, 3-times folded
e) 16 layers, 4-times folded

Figure 13 — Folding and assembling the test pack

24.1.6 After equilibration the sheets shall be folded to approximately 220 mm × 300 mm and stacked to a height of approximately 250 mm after compression by hand. The pack shall be wrapped in a similar fabric and secured with tape not exceeding 25 mm in width. The total weight of the pack shall be 7,0 kg ± 0,14 kg. (Approximately 30 sheets are required for this.) After processing the pack shall be removed from the sterilizer and aired in an environment of between 20 °C to 30 °C and relative humidity of between 40 % to 60 %. The pack may then be used for testing. The pack shall be equilibrated in an environment of between 20 °C to 30 °C and relative humidity of between 40 % to 60 % between uses.

NOTE After use, the sheets will become compressed. When the weight of sheets used to form a stack 250 mm high exceeds 7,14 kg, the sheets should be discarded.

24.1.7 Prior to use the temperature and humidity of the pack shall be measured using a suitable calibrated temperature and humidity probe. The conditions within the pack shall be between 20 °C to 30 °C and 40 % to 60 % relative humidity before it is used for test purposes.

NOTE Pack temperature and humidity may be measured using a sword hygrometer.

24.1.8 Test packs comprising different materials and of different sizes and weights can be used provided equivalence with the requirements for the test in which the standard test pack is used is demonstrated.

24.2 Reduced test pack

24.2.1 This test pack is used in a one module sterilizer to check that, at the levels at which the process variables are set, rapid and even penetration of steam into the pack is attained.

It is used for the Bowie and Dick test, the small load tests, air detector tests, load dryness test, textiles and can be used with other materials to form a full load.

The test pack is a reusable item that may be used for testing continuously if the requirements in 24.2.3 and 24.2.4 are met. The environmental aspects regarding cleaning intervals as well as means for cleaning and conditioning should be considered.

24.2.2 The test pack shall be composed of plain cotton sheets, each bleached to a good white and having an approximate size of 900 mm x 1 200 mm. The number of threads per centimetre in the warp shall be (30 ± 6) and the number of threads per centimetre in the weft (27 ± 5), the weight shall be (185 ± 5) g/m², the edges, which are no self-edges shall not be hemmed.

24.2.3 The sheets shall be washed when new or soiled and shall not be subjected to any fabric conditioning agent during laundering.

NOTE Fabric conditioning agents can affect the characteristics of the fabric and can contain volatiles which will contribute to the non-condensable gases in the sterilizer.

24.2.4 The sheets shall be dried and then allowed to equilibrate in an environment of between 20 °C to 30 °C and a relative humidity of 40 % to 60 %.

24.2.5 The test pack shall be folded and assembled in accordance with Figure 13.

24.2.6 After equilibration the sheets shall be folded to approximately 220 mm × 300 mm and stacked to a height of approximately 150 mm after compression by hand. The pack shall be wrapped in a similar fabric and secured with tape not exceeding 25 mm in width. The total weight of the pack shall be 4,0 kg ± 0,16 kg. (Approximately 17 sheets are required for this.) After processing the pack shall be removed from the sterilizer and aired in an environment of between 20 °C to 30 °C and relative humidity of between 40 % to 60 %. The pack may then be used for testing. The pack shall be equilibrated in an environment of between 20 °C to 30 °C and relative humidity of between 40 % to 60 % between uses.

NOTE After use, the sheets will become compressed. When the weight of sheets used to form a stack 150 mm high exceeds 4,16 kg, the sheets should be discarded.

24.2.7 Prior to use the temperature and humidity of the pack shall be measured using a suitable calibrated temperature and humidity probe. The conditions within the pack shall be between 20 °C to 30 °C and 40 % to 60 % relative humidity before it is used for test purposes.

NOTE Pack temperature and humidity may be measured using a sword hygrometer.

24.3 Pressure instruments

24.3.1 A test measurement system shall be used to check pressure indicating and recording instruments.

NOTE The system may include one or more test gauges or instrumentation incorporating transducers.

24.3.2 The resolution shall not exceed 1 kPa over the range 0 kPa to 400 kPa and for instruments used for air leakage test the resolution shall not exceed 0,1 kPa over the range used [see 24.3.3 b)].

24.3.3 The test measurement system shall:

a) have a scale range which includes 0 kPa to 400 kPa (-1 bar to 3 bar) and an accuracy class over this range of at least 0,25;

b) if used for the air leakage test have a scale range specified by the manufacturer of the sterilizer and have an accuracy of not less than 0,1 kPa (1 mbar) over any pressure difference of 1,5 kPa (15 mbar) over the pressure range that may occur during the test.

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.

24.3.4 Calibration of each test system shall be carried out using a working or reference standard, which is traceable to the national standard or a primary standard.

24.3.5 Each test system shall be calibrated in accordance with the manufacturer's instructions.

24.4 Temperature sensors

24.4.1 Temperature sensors shall be used to sense the temperature in locations specified in the tests described in this European Standard.

24.4.2 Temperature sensors shall be either platinum resistance and comply with Class A of EN 60751:1995 or thermocouple and comply with one of the tables of Tolerance Class 1 of EN 60584-2:1993 and have a response time in water of $\tau_{90} \leq 0{,}5$ s.

NOTE Other sensors of demonstrated equivalence can be used.

24.4.3 The cross sectional area of any part of the sensor and its connecting wires within the usable space shall not exceed 3,1 mm^2.

24.4.4 The performance characteristic for the temperature sensor shall not be affected by the environment in which it is placed, e.g. pressure, steam, or vacuum.

24.5 Thermometric recording instrument

24.5.1 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 European Standard. It can also be used to check thermometric instruments fitted to the sterilizer.

24.5.2 The recording instrument shall record the temperature from a minimum of seven temperature sensors. The channels can be multiplexed or independent of each other. The sampling rate for each channel shall be 1 s or less. All data sampled shall be used for the interpretation of the results.

24.5.3 The scale range for analogue instruments shall include 0 °C to 150 °C. The minor mark interval shall not exceed 1 C and the chart speed shall be not less than 15 mm/min. The resolution shall be better than 0,5 °C.

24.5.4 Digital instruments shall register and record in increments of not more than 0,1 °C and the scale range shall include 0 °C to 150 °C.

24.5.5 The limit of error between 0 °C to 150 °C (excluding temperature sensors) shall not exceed ± 0,25 % when tested in an ambient temperature of (20 ± 3) °C.

24.5.6 The additional error due to the change in the environmental temperature shall not exceed 0,04 K/K.

24.5.7 Calibration shall be carried out using a working or reference standard which is traceable to the national standard or a primary standard.

24.5.8 The instrument shall be calibrated in accordance with the manufacturer's instructions and calibration shall include a temperature within the sterilization temperature band. The temperature measured by all temperature sensors when immersed in a temperature source at a temperature known within ± 0,1 °C and within the sterilization temperature band shall not differ by more than 0,5 °C after calibration.

24.5.9 When installed in the place of use, the temperature system shall be verified with an independent temperature reference source at a temperature within the sterilization temperature band.

24.5.10 The temperature reference source shall have the following features:

— it shall incorporate a reference thermometer which is traceable to the national standard or a primary standard and shall include the range 110 °C to 140 °C. The minor mark interval shall not exceed 0,2 °C;

— it shall incorporate a pocket, sized to accommodate a minimum of seven temperature sensors as described in 24.4. The temperature gradient within the pocket shall not exceed 0,2 °C and the control accuracy shall be within ± 0,1 °C over the range of 100 °C to 140 °C.

24.6 Pressure recording instrument

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

24.6.2 The instrument may be integrated into the temperature recording instrument as an additional channel calibrated for pressure. The sampling rate for each channel shall be 1 s or less. All data sampled shall be used for the interpretation of the results.

24.6.3 The scale range for analogue instruments shall include 0 kPa and 400 kPa (-1 bar and 3 bar). The minor mark interval shall not exceed 4 kPa (0,04 bar) and the chart speed shall be not less than 15 mm/min. The resolution shall be better than 2 kPa (0,02 bar).

24.6.4 Digital instruments shall register and record in increments of not more than 1 kPa (0,01 bar) and the scale range shall include 0 kPa and 400 kPa (-1 bar and 3 bar).

24.6.5 The limit of error between 0 kPa and 400 kPa (-1 bar and 3 bar), of the measuring system shall not exceed ± 0,5 % when measured in an ambient temperature at (20 ± 3) °C.

24.6.6 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.

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

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

24.6.9 Calibration shall be carried out using a working or reference standard which is traceable to the national standard or a primary standard.

24.6.10 The instrument, when connected to a pressure sensitive element, shall be calibrated in accordance with the manufacturer's instructions and calibration shall include those pressures corresponding to control points within the sterilization cycle, see Figure 4.

24.7 Full load, textiles

24.7.1 This test load is designed to represent the maximum mass of textiles which can be processed in the sterilizer and is used to demonstrate that, at the levels at which cycle variables are set, rapid and even penetration of steam into the centre of a load occurs and the sterilizing condition is achieved.

The full load textiles consist of reusable items that may be used for testing continuously if the requirements in 24.7.3 and 24.7.4 are met. The environmental aspects regarding cleaning intervals as well as means used for cleaning and conditioning should be considered.

24.7.2 The full load shall comprise folded sheets and a standard test pack as described in 24.1.

24.7.3 Each sheet shall contain at least 50 % m/m of cotton fibre and have a mass per unit area of approximately 200 g/m². The sheets shall be laundered when new or soiled and not subjected to any fibre conditioning agent (see 24.1).

24.7.4 The sheets shall be dried and then aired for at least 1 h in an environment between 20 °C and 30 °C and at a relative humidity 40 % to 60 %.

NOTE If the environment in which the sheets are aired or stored is dryer than stated errors may occur due to exothermic re-hydration of the test pack in the sterilizer.

24.7.5 After airing, the sheets shall be folded and laid one on top of the other to form a stack with a mass of (7,5 ± 0,5) kg.

24.7.6 The standard test pack shall be located within the sterilizer chamber and in a position identified by the manufacturer as the most difficult to sterilize. The remainder of the usable space shall be loaded with stacks of sheets each with the layers of fabric in the baskets dimensionally similar to one sterilization module or they can be loose within the sterilizer chamber.

24.7.7 The mass of fabric in the test load shall be equivalent to (7,5 ± 0,5) kg per load module.

[A1] *deleted text* [A1]

24.8 Test pack, metal

24.8.1 This test pack is used to represent a unit of metal objects, e.g. instruments, which is difficult to dry.

The test pack metal consists of reusable items that may be used for testing continuously.

24.8.2 Sterilizer load shall comprise a test box containing a wire mesh basket and a quantity of metal screws wrapped in textile material.

24.8.3 The test box shall:

- have a sealed lid and comply with the detail given in Figure 14;
- not have additional holes to those shown in Figure 14;
- be constructed from 1 mm (nominal) thick austenitic stainless steel according to EN 10088-3.

24.8.4 The wire mesh basket shall:

- be constructed from austenitic stainless steel according to EN 10088-3;
- have a nominal grid size on the base of 5 mm × 5 mm;
- have a nominal grid size on the sides of 5 mm × 5 mm;
- have a load surface separated from the support surface by approximately 6 mm;
- be capable of supporting an evenly distributed load of 10 kg;
- have external dimensions of length (480 ± 5) mm, width (254^{0}_{-4}) mm, and height (50^{+5}_{0}) mm;

— have a mass of (1,3 ± 0,1) kg.

24.8.5 The metal screws used in the test load shall:

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

— be hexagon head screws EN ISO 4017-M12 × 100;

— have a total mass of (8,6 ± 0,1) kg;

— be cleaned, degreased and dried.

24.8.6 The textile material used in the test shall:

— be a plain cotton sheet, bleached white and having an approximate size of 900 mm × 1 200 mm;

— have a number of threads per centimetre in the wrap of (30 ± 6) and a number of threads per centimetre in the weft of (27 ± 5);

— be washed when new and when soiled and not subjected to any fabric conditioning agent;

— be dried and aired;

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

NOTE This requirement assumes that before packaging components have been allowed to equilibrate to the local environment.

24.8.7 All metal parts in the test pack shall be equilibrated to a temperature of (23 ± 2) °C.

24.8.8 The test pack shall be assembled as follows:

— place the wire mesh basket onto the sheet;

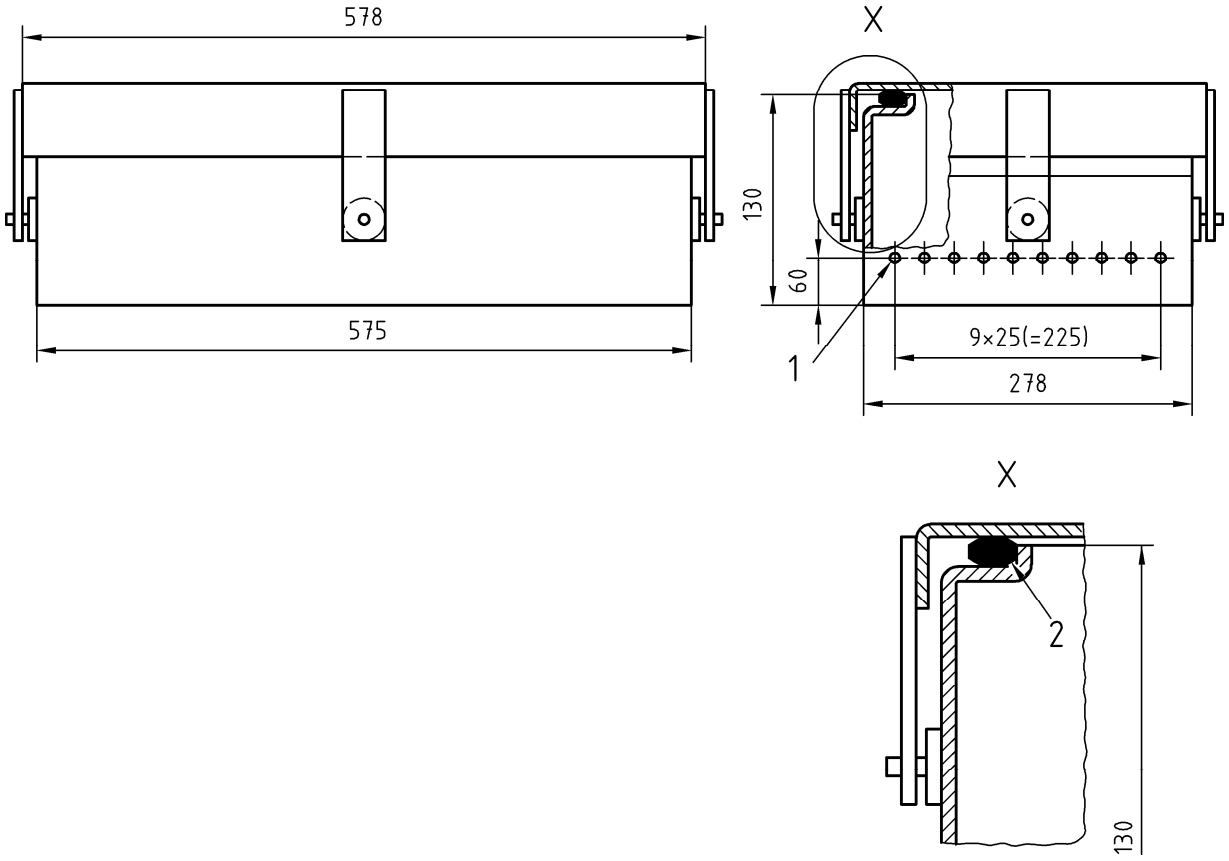
— distribute the screws randomly throughout the wire mesh basket in a manner which allows the free drainage of condensate;

— fold the sheet over the wire mesh basket containing the screws;

— place the wrapped wire mesh basket into the test box.

24.8.9 Store the test pack until required in an environment maintained within the limits specified for the items used to form the test pack.

Dimensions in millimetres



Key

1 10 drill holes Ø 4 mm on both end walls

2 silicon sealing Ø 6 × 1 550, glued to the lid and compressed to 90 % of its diameter when the lid is closed.

Figure 14 — Details of test box for metal test

24.9 Metering device

24.9.1 A metering device is used to admit air to the sterilizer chamber to test that a process monitoring device will indicate a fault when the mass of air present in the sterilizer chamber is sufficient for the sterilization cycle to be of uncertain efficacy.

24.9.2 The device shall be capable of controlling the flow of air into an evacuated sterilizer chamber.

24.9.3 The device shall be adjustable and have a range which includes a flow equivalent to 0 ml/min · l to 5 ml/min · l of the sterilizer chamber.

24.9.4 The error in repeatability between 10 % and 90 % of the setting range shall not exceed ± 5 %.

25 Documentation to be supplied by the manufacturer

25.1 Records of tests and checks sufficient to assure the purchaser that the sterilizer has been manufactured in accordance with the specification shall be provided (see also 26.3).

25.2 The documentation shall include:

a) evidence of verification of the calibration of all instrumentation (see EN ISO 10012);

b) evidence of verification that the function of each safety device and its setting complies with the specification (see EN 61010-2-040);

c) details of the settings of the automatic controller together with pressures, temperatures and times taken for each significant part of the sterilization cycle, e.g. change from each stage or sub-stage;

d) the setting of the air detector if one is fitted;

e) declaration of compliance with the requirements of this European Standard (see Clause 14);

f) declaration of additional cycles and their intended use not covered by this European Standard.

26 Information to be supplied by the manufacturer

26.1 The objective of Clause 26 is to enable the purchaser to prepare for installation, to install and operate the sterilizer and to perform routine maintenance.

The information specified in 26.2, 26.3 and 26.4 shall be provided either in one part prior to delivery of the sterilizer or in two parts, prior to delivery and before installation qualification.

26.2 Before delivery of the sterilizer and for installation qualification, the following information shall be provided to the purchaser:

a) installation instructions, including the overall dimensions and overall mass of the sterilizer, the floor loading at each support when the sterilizer pressure vessel is filled with water, the clearance required for access and the masses of the principal heavy components;

b) type of electricity supply, e.g. DC or AC, single or three phase, voltage and frequency including minimum and maximum values and maximum continuous power in kilowatts and kilovolt-amperes;

c) the maximum flow and usage rate and the maximum and minimum supply pressure for steam;

d) the quality and quantity of the steam to be supplied for use with the sterilizer, (see Table B.2);

e) the minimum and maximum pressure and flow at minimum pressure, volume used per cycle for water and feed water;

f) the minimum and maximum pressure and flow at minimum pressure for compressed air;

g) the total thermal power in watts transmitted from the sterilizer when it is operated in an ambient temperature of (23 ± 2) °C in still air when the door is open and also when the door is closed;

NOTE 1 When designing the ventilation system the user should take into account the heat transmitted by the sterilized load.

h) the thermal power in watts transmitted from the front of the sterilizer when it is operated in an ambient temperature of (23 ± 2) °C in the working area and when the door is open and also when it is closed;

i) the calculated A-weighted sound power level in decibels to the nearest integer and the maximum impulsive noise index, also to the nearest integer;

j) the sound power level for any additional devices supplied by the sterilizer manufacturer for use with the sterilizer;

k) the type of doors and information on the necessary space required for the movement of the door(s);

NOTE Additional space can be required for loading and unloading equipment.

l) the maximum flow of water and condensed steam to the drain;

m) the maximum hardness value, the range of pH and the conductivity of the feed water (see Table B.1);

n) instructions for disposal of the sterilizer wrapping;

o) any additional device i.e. air compressor which is necessary for the operation of the sterilizer and which is installed separately from it;

p) details of services required for supply, drainage and ventilation;

q) environmental classification for the sterilizer (see 13.6);

r) the depth of vacuum needed to comply with the requirements for the tests specified in this European Standard.

26.3 Before the installation qualification, the following information shall be provided (see Clause 25):

a) operating instructions, short form of manual;

b) user instructions with at least:

- range of application;
- type of load ▌A1⟩ and its packaging ⟨A1▐;
- total volume;
- design pressure, allowable working pressure and allowable temperature;
- description of the available sterilization cycles;
- description of controls, indicating and recording devices;
- description and setting of safety devices;
- instructions for malfunctions;
- instructions for cleaning the panelling;
- characteristics of consumables and accessories dedicated to the sterilizer;
- instructions for cleaning and cleaning agents to be used;

c) dimensions of the usable space of the pressure vessel;

d) loading capacity expressed in sterilization modules in integer numbers;

e) a description of the sterilization cycle together with:

- the maximum operating temperature;
- a diagram of the pressure versus time relationship for the sterilization cycle(s);
- a temperature versus time record of the sterilization cycle for each standard test load applicable to the sterilizer supplied;
- parameters critical to the sterilization cycle (see 7.1.3);

— tolerances for the parameters critical for the sterilization cycle;

— the location of the reference measurement point (see 7.1.4);

NOTE If requested, documentary evidence to show the relationship between the coolest part of the usable space and the reference measurement point should be provided.

f) information on safety details (e.g. door-locking mechanism);

g) maintenance manual including:

— maintenance and tests and the frequency they should to be carried out;

— electrical diagrams and circuits;

— hydraulic plans and circuits;

— a complete spare parts list;

— a list of the tools necessary for maintaining and testing the apparatus (only special tools);

— type of guarantee offered;

— list of service stations;

— guidance on tracing and rectifying causes of malfunction;

h) instructions for disposal of the sterilizer, the consumables and accessories;

i) leak rate;

j) information on the tests to be performed during installation qualification and operational qualification (see also Annex E).

26.4 The information required by 26.2 and 26.3 shall be provided for any steam generator included within the panelling of the sterilizer, if applicable.

Annex A
(informative)

Environmental aspects

A.1 Environmental aspects regarding the life cycle of steam sterilizers

A.1.1 Sterilization with steam (brief environmental review)

The initial resource used at sterilization with steam is potable water eventually further refined by commercially established softening-, demineralising- or de-ionising methods.

The water is used in both its gaseous and liquid state of aggregation. The gaseous state of aggregation, called saturated steam, is used for thermal sterilization because of its very large and self-emitting energy content, which is used to kill microorganisms. The liquid water is used for steam production, eventually as an operational media for air removal to obtain sterilization conditions, and as a cooling media to restore gaseous steam into liquid with an appropriate temperature for disposal.

A.1.2 Environmental impact

Vaporisation of water into different states of steam and restoration of the steam into water by condensation is a recyclable process and a vital part of our ecology. Consequently, the principles itself for steam sterilization do not add any specific burden on the environment.

Steam is not toxic, irritating or allergenic, and has no detrimental impact on the local environment or human beings, except for the risk of burn injuries at accidental human exposure.

The environmental impact generated by a sterilizer performing steam sterilization is mainly isolated to the following occurrences:

- the use of water and energy resources for generating saturated steam during testing and normal use;
- the use of water resources for operational and cooling purposes during testing and normal use;
- impact at local environment during normal use;
- disposal of contaminated wastewater during normal use;
- use, cleaning and disposal of usables during testing and normal use;
- scrapping at the end of the life cycle.

To highlight the importance of reducing the environmental burden, this European Standard addresses requirements or recommendations intended to decrease environmental impact caused by those aspects during different stages of the sterilizer life cycle.

Table A.1 — Environmental aspects addressing clauses of this European Standard

Environmental aspects (inputs and outputs)		Product life cycle			
		Production and preproduction Stage A	Distribution (including packaging) Stage B	Use Stage C	End of life Stage D
		Addressed in clause	Addressed in clause	Addressed in clause	Addressed in clause
1	Resource use	1.4 Table 4 [A2] Table E.1 [A2] 24.1.1 24.2.1 24.7.1 [A1] *deleted text* [A1] [A1] 24.8.1 [A1]	1.4	1.4 5.4 14.3 [A1] NOTE in 15.3.2 [A1] 16.1.3.5, 16.2.3.5, 17.3.2, 19.2.2.7, 19.3.2.8, 19.4.3.4, 20.1.3.4, 20.2.3.4, 20.3.3.4 and in 22.3.2.6 Table 4 Table E.1 24.1.1, 24.1.2 24.2.1, 24.2.2 24.7.1 [A1] *deleted text* [A1] [A1] 24.8.1 [A1] 26.2	1.4 26.3
2	Energy consumption	1.4 Table 4 [A2] Table E.1 [A2]	1.4	1.4 4.3.4 5.1.2 14.3 [A1] NOTE in 15.3.2 [A1], 16.1.3.5, 16.2.3.5, 17.3.2, 19.2.2.7, 19.3.2.8, 19.4.3.4, 20.1.3.4, 20.2.3.4, 20.3.3.4 and in 22.3.2.6 Table 4 Table E.1 26.2	-

Table A.1 (*continued*)

Environmental aspects (inputs and outputs)		Product life cycle			
		Production and preproduction Stage A	Distribution (including packaging) Stage B	Use Stage C	End of life Stage D
		Addressed in clause	Addressed in clause	Addressed in clause	Addressed in clause
3	Emission to air	1.4	1.4	1.4 4.2 4.3.4 4.4.1 5.1.2 13.6 13.7 13.9 14.3 ⟨A1⟩ NOTE in 15.3.2 ⟨A1⟩, 16.1.3.5, 16.2.3.5, 17.3.2, 19.2.2.7, 19.3.2.8, 19.4.3.4, 20.1.3.4, 20.2.3.4, 20.3.3.4 and in 22.3.2.6 26.2 Annex E	1.4 26.2
4	Emission to water	1.4 5.4 24.1.1 24.2.1 24.7.1	1.4	1.4 4.2 4.4.1 ⟨A2⟩ 5.2.2.2 ⟨A2⟩ 5.4 13.7 14.3 ⟨A1⟩ NOTE in 15.3.2 ⟨A1⟩, 16.1.3.5, 16.2.3.5, 17.3.2, 19.2.2.7, 19.3.2.8, 19.4.3.4, 20.1.3.4, 20.2.3.4 and in 20.3.3.4 24.1.1, 24.1.2 24.2.1, 24.2.2 24.7.1 26.2 26.3 C.1.2 Annexes B and E	1.4 26.2

Table A.1 (*continued*)

Environmental aspects (inputs and outputs)		Product life cycle			
		Production and preproduction Stage A	Distribution (including packaging) Stage B	Use Stage C	End of life Stage D
		Addressed in clause	Addressed in clause	Addressed in clause	Addressed in clause
5	Waste	1.4 Table 4 [A2] Table E.1 [A2] [A1] NOTE in 15.3.7 [A1] 17.3.6 24.1.1 24.2.1 24.7.1 [A1] *deleted text* [A1] [A1] 24.8.1 [A1]	1.4 26.2	1.4 14.3 NOTE in 15.2.3, 16.1.3.5, 16.2.3.5, 17.3.2, 19.2.2.7, 19.3.2.8, 19.4.3.4, 20.1.3.4, 20.2.3.4 and in 20.3.3.4 Table 4 [A2] Table E.1 [A2] [A1] NOTE in 15.3.7 [A1] 17.3.6 24.1.1, 24.1.2 24.2.1, 24.2.2 24.7.1 [A1] *deleted text* [A1] [A1] 24.8 [A1] 26.2 26.3 C.1.2	1.4 26.3
6	Noise	-	-	1.4 26.2 4.4.1 9 14.3 [A1] NOTE in 15.3.2 [A1], 16.1.3.5, 16.2.3.5, 17.3.2, 19.2.2.7, 19.3.2.8, 19.4.3.4, 20.1.3.4, 20.2.3.4 and in 20.3.3.4	-

Table A.1 (*continued*)

Environmental aspects (inputs and outputs)		Product life cycle			
		Production and preproduction Stage A	Distribution (including packaging) Stage B	Use Stage C	End of life Stage D
		Addressed in clause	Addressed in clause	Addressed in clause	Addressed in clause
7	Migration of hazardous substances	Table 4 [A2] Table E.1 [A2] [A1] NOTE in 15.3.7 [A1] 17.3.6	-	1.4 4.2 13.4 [A2] Table E.1 [A2] [A1] NOTE in 15.3.7 [A1] 17.3.6 26.3 C.1.2 Annex B	1.4 26.3
8	Impacts on soil	-	-	-	1.4 26.3
9	Risks to the environment from accidents or misuse	1.4	-	1.4 4.2 4.4.3 5.2.2 7.1.3 7.1.5 7.1.6 7.1.8 7.1.9 7.1.10 7.1.12 7.2.1 7.2.3 7.2.4 [A1] 8.2.3 [A1] 11 12.1 13.3.7 13.4 26.2 26.3 Annex E	1.4 26.3
NOTE Several common references in stages A and C above are made regarding testing as testing procedures is requested by this European Standard during both stages of the life cycle (see categories of tests in Clause 14 of this European Standard).					

Annex B
(informative)

Steam supply; suggested maximum values of contaminants in feed water and condensate

Table B.1 — Contaminants in feed water supplied to a dedicated steam generator

Determinand	Feed water
Residue on evaporation	≤ 10 mg/l
Silicate (SiO_2)	≤ 1 mg/l
Iron	≤ 0,2 mg/l
Cadmium	≤ 0,005 mg/l
Lead	≤ 0,05 mg/l
Rest of heavy metals except iron, cadmium, lead	≤ 0,1 mg/l
Chloride (Cl')	≤ 2 mg/l
Phosphate (P_2O_5)	≤ 0,5 mg/l
Conductivity (at 25 °C)	≤ 5 µS/cm
pH value (degree of acidity)	5 to 7,5
Appearance	Colourless clean without sediment
Hardness (Σ Ions of alkaline earth)	≤ 0,02 mmol/l
NOTE Compliance should be tested in accordance with acknowledged analytical methods.	

Table B.2 — Contaminants in condensate from steam supply to the sterilizer measured at the sterilizer inlet

Determinand	Condensate
Silicate (SiO_2)	≤ 0,1 mg/ l
Iron	≤ 0,1 mg/ l
Cadmium	≤ 0,005 mg/l
Lead	≤ 0,05 mg/l
Rest of heavy metals except iron, cadmium, lead	≤ 0,1 mg/l
Chloride (Cl')	≤ 0,1 mg/l
Phosphate (P_2O_5)	≤ 0,1 mg/l
Conductivity (at 25 °C)	≤ 3 µS/cm
pH value (degree of acidity)	5 to 7
Appearance	Colourless clean without sediment
Hardness (Σ Ions of alkaline earth)	≤ 0,02 mmol/l
NOTE A method by which a sample of condensate can be taken is given in 22.4.	

Annex C
(informative)

Recommended materials

C.1 General

C.1.1 This annex contains a survey and a selection of materials as a guide for use in the manufacture of a steam sterilizer. In the selection of materials, national regulations are taken into account. For this reason, it is not intended, nor is it possible, that the information given in this annex should remove the decision making responsibility from the manufacturer for the selection of an appropriate material with suitable properties, nor is it intended to preclude the use of other types of materials demonstrating at least equivalent qualities. Ten groups of combinations are recognized. These are referred to as Groups A to K. Tables C.1, C.2 and C.3 illustrate these combinations.

C.1.2 When selecting materials, the following factors should be considered:

— the possible corrosive influence of the goods to be sterilized within the sterilizer chamber;

— the existence of corrosion promoting substances in the sterilizing steam or cooling agents (e.g. free oxygen or carbon dioxide);

— the possibility of forming corrosion resistant layers at surfaces;

— environmental aspects (e. g. migration of substances and scrapping at end of life).

C.1.3 Tables C.1, C.2 and C.3 illustrate the combinations of the following materials numbered as I to VII. Examples for the materials I, II, III, IV, V and VI are given in Table C.4.

I Stainless steel

II Carbon steel

III Carbon steel, clad

IV Copper

V Aluminium, aluminium alloys

VI Copper alloys

VII Other

Table C.1 — Combination of materials

Vessel components for sterilizers and for steam generators	Suggested combinations of materials			
	Group A	Group B	Group C	Group D
Chamber	I	III	IV	V
Jacket	I	II	IV	V
Door	I/III	I/III	IV/VI	V
Internal chamber equipment	I	I	VI	V
External frame for vessel	I/II	II	IV	V
Cladding	I[a]	I[a]	I[a]	I/V
Frame	I/II	II	II	II/V
Steam generator integral to the chamber	I/III	III	IV	V
Steam generator inside the frame or free standing	I/III	I/III	IV	I/III

[a] Coated or other corrosion resistant cladding can be used where stainless steel is not appropriate.

C.2 Pipework and fittings

C.2.1 Media coming into contact with loads:

a) steam for sterilization;

b) demineralized water;

c) sterile air;

d) condensate.

Table C.2 — Combinations of materials

Pipework for circulation media coming into contact with loads	Suggested combinations of materials		
	Group E	Group F	Group G
Pipes	I	I	IV
Fittings	I	I	VI
Loose flanges	II	II	II
Flanges for welding	I	I	– –
Collars (weldings)	I	I	IV
Valve housings	I	VI	VI
Valve cones and gaskets	I	I	VI
Sensors	I	I	IV
Pipes for pressure gauges	I	IV	IV
Pressure gauges	I	VI	IV/VI
NOTE To prevent transmission of noise and vibration, elastomeric or flexible metal connectors should be considered for part of the sterilizer pipework. Such connectors should be subject to the same consideration of suitability as the pipe into which they are connected.			

C.2.2 Media not coming into contact with goods:

a) steam for industrial use;

b) cooling water;

c) drain water;

d) compressed air for control purposes;

e) steam and/or air under vacuum.

Table C.3 — Combinations of materials

Pipework for circulation media not coming into contact with loads	Suggested combinations of materials		
	Group H	Group J	Group K
Pipes	IV	IV/II	IV/II
Fittings	IV/VI	II/VI	II/VI
Loose flanges	II	II	II
Flanges for welding	– –	II	II
Collars (weldings)	IV	IV	IV
Valve housings	VI	VI	VI
Valve cones and gaskets	I/VI	VI	VI
Sensors	I	I	IV
Pipes for pressure gauges	I	IV	IV
Pressure gauges	I	IV/VI	IV/VI
Compressed air pipes for valve control	VII	VII	VII
NOTE To prevent transmission of noise and vibration, elastomeric or flexible metal connectors should be considered for part of the sterilizer pipework. Such connectors should be subject to the same consideration of suitability as the pipe into which they are connected.			

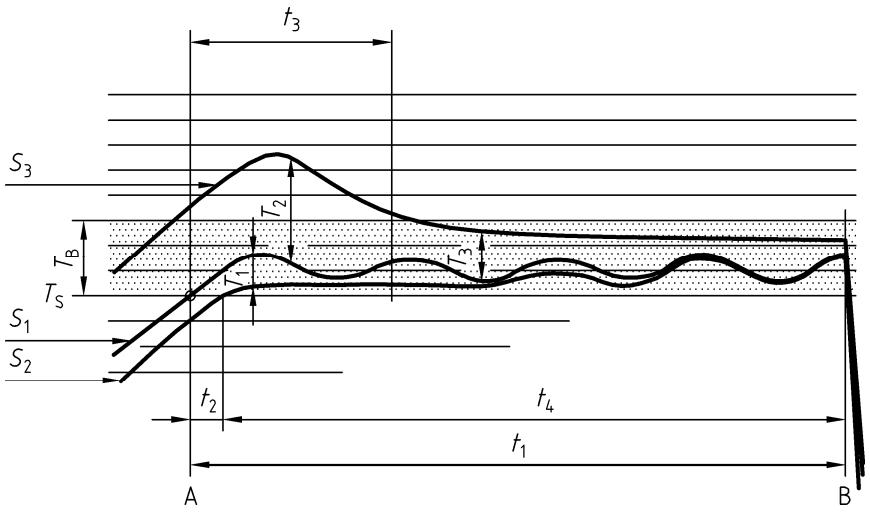
Table C.4 — Examples for the materials I, II, III, IV, V and VI

Group of material	Examples of standards	Grade of material
I	EN 10088-1, -2, -3	X6CrNiMoTi17-12-2 X6CrNiTi18-10 X5CrNi18-10 X2CrNiMo17-12-2
II and III	EN 10025 EN 10095 EN 1562	Fe 360-BFN X 10 CrNiTi 18 10 EN-GJMW-450-7
IV and V	EN 1652; EN 1653 EN 12449, EN 12451 EN 1982	Cu-DHP G-CuSn 10 Zn CuZn39Pb0,5
V	EN 573-3; EN 573-4	EN AW AlMg3

Annex D
(informative)

Temperature and time tolerances during the small load thermometric test

Temperature and time tolerances during the small load thermometric test are illustrated in Figure D.1.



Key

A	start of plateau period	S_1	trace of sensor at the measurement reference point
B	end of plateau period	S_2	[A1] trace of the sensor showing the lowest temperature in the test pack [A1]
T_s	sterilization temperature	S_3	trace of sensor 50 mm above the test pack
T_B	sterilization temperature band	T_1	maximum difference between reference temperature and temperature in the test pack during holding time
t_1	plateau period	T_2	maximum difference between reference temperature and temperature above test pack within the first 60 s of plateau period
t_2	equilibration time	T_3	maximum difference between reference temperature and temperature above the test pack during the plateau period after the first 60 s
t_3	60 s		
t_4	holding time		

Figure D.1 — Temperature and time tolerances during the small load thermometric test

Annex E
(informative)

Guidance for installation and operational qualification tests to be included in the instructions for use supplied with a sterilizer

When installed into its site of operation and connected to the specified services designated by the manufacturer a sterilizer will need to be subjected to a number of installation qualification (IQ) and operational qualification (OQ) tests as required by prEN ISO 17665. A suggested list of tests is contained in Table E.1.

Whilst the requirements of local regulations/guidance will need to be followed the tests listed in Table E.1 may be used as part of the IQ/OQ process. When assessing the suitability of each test due regard should be paid to the intended use of the sterilizer and load items likely to be processed.

Where sterilizers are used for particular loads specific OQ/performance qualification (PQ) tests will be described for such loads (see prEN ISO 17665). A test listed for OQ in Table E.1 is applicable only when in accordance with the intended use of the sterilizer or its equipment.

Table E.1 — Suggested tests

Test	Requirements according to	Test according to	Installation Qualification	Operational Qualification
Safety Tests and checks	See Clause 11		XX	-
Steam quality tests				
- Non-condensable gases	13.3.2	22.1	X	X
- Dryness value	13.3.3	22.2	X	X
- Superheat	13.3.4	22.3	X	X
- Contaminants	see Table E.2	[a]	X	X
Thermometric tests				
- Small load	[A1] 8.2.1.2	16.1	-	XX
- Full load	8.2.1.3 [A1]	16.2	-	XX
[A1] Hollow load test [A1]	[A1] 8.2.5 [A1]	[A1] 15 [A1]	[A1] - [A1]	[A1] XX [A1]
Bowie and Dick test	[A1] 8.2.2 [A1]	17	-	XX
Air leakage flow rate	[A1] 8.2.3 [A1]	18	-	XX
Air detector				
- Small load	[A1] 8.2.4.2	19.2	-	XX
- Full load	8.2.4.3	19.3	-	XX
- Function	8.2.4.4 [A1]	19.4	-	XX

Table E.1 (*continued*)

Test	Requirements according to	Test according to	Installation Qualification	Operational Qualification
Load dryness tests				
- Small load, textiles	[A1] 8.3.1	20.1	-	X
- Full load, textiles	8.3.2	20.2	-	XX
- Metal	8.3.3 [A1]	20.3	-	X
Dynamic pressure test	10	23	-	X

XX tests which are suggested

X tests which may be considered

- tests which need not be performed during IQ and/or OQ

[a] Compliance should be tested in accordance with acknowledged analytical methods.

Table E.2 — Contaminants in condensate from steam used by the sterilizer to be considered in relation to contamination of the load

Determinand	Clean steam condensate
Acidity or alkalinity	R[a]
Ammonium (NH_4)	≤ 0,2 mg/l
Calcium and magnesium	R[a] (mg/l)
Heavy metals	≤ 0,1 mg/l
Chloride (Cl')	≤ 0,5 mg/l
Nitrate (NO_3)	≤ 0,2 mg/l
Sulphate (SO_4)	R[a] (mg/l)
Oxidisable substances	R[a]
Residue on evaporation	≤ 30 mg/l
Silicate (SiO_2)	≤ 0,1 mg/l
Phosphate (P_2O_5)	≤ 0,1 mg/l
Conductivity (25 °C)	≤ 35 µS/cm
Bacterial endotoxins	≤ 0,25 EU/ml
Appearance	Clear, colourless

[a] R reagent test specified in European Pharmacopeia

NOTE A method by which a sample of condensate can be taken is given in 22.4.

Annex F
(informative)

Criteria for identifying sterilizers as the same type

F.1 Sterilizers classed as the same type should have:

— the same number of doors in the same configuration; where it has been demonstrated that for a given size and type of door, there is no difference in the influence on the load between a door and a back plate, sterilizers with one or two of these doors do not constitute different types;

— all service connections into the sterilizer chamber in the same orientation; a mirror image of the original orientation does not constitute a new type;

— the same control system with all sensors located in the same position and orientation; any change in the control system that does not affect the process sequence and the limiting values does not constitute a new type;

— the same sterilization cycle.

Whenever the designed operating characteristics of the air removal stage of the sterilization cycle are changed the sterilizing efficacy in small, full and ⟨A1⟩ hollow ⟨A1⟩ loads, as appropriate, should be demonstrated. This may be achieved using the test(s) specified in Clauses 15 and 16.

F.2 If all other aspects of design remain the same the following variations should not constitute a new type:

— height of sterilizer chamber location above the floor;

— differences in the dimensions of the sterilizer chamber not greater than ± 10 % of the dimensions with congruent sterilizer chamber shapes;

— increasing the time of the plateau period within the sterilization cycle having the same sterilization temperature and the same air removal stage;

— any change of the design or provenance of equipment providing there is available documented evidence to show there is no adverse effect on the performance of the sterilizer which would effect compliance with this European Standard.

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 standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA confers, within the limits of the scope of this 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

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4, 5, 6, 7, 8, 9, 10, 11	1	
4, 5, 6, 7, 8, 9, 11	2	
6, 7, 8, 10	3	
4, 5, 6, 7, 8, 10, 11	4	
	5	not covered
9, 11	6	
4, 5, 6, 7, 8, 11	7	
4, 5, 7	8	Features of sterilizers specified which permit validation to be performed
4, 5, 6, 7, 8, 9, 11, 13, 25, 26	9	
	10	not applicable
11, 13	11	
5, 6, 7, 11, 13	[A2] 12 [except 12.1 a)] [A2]	
[A2] -	12.1 a)	This relevant Essential Requirement is not addressed in this European Standard [A2]
12, 25, 26	[A2] 13 [except 13.6 q)] [A2]	[A2] the relevant Essential Requirement 13.3 a) is partly addressed [A2]
[A2] 12.2, 26.3 g)	13.3 a)	This relevant Essential Requirement is partly addressed in this European Standard
-	13.6 q)	This relevant Essential Requirement is not addressed in this European Standard [A2]
	14	not applicable
15, 16, 17, 18, 19, 20, 21, 22, 23, 24		test methods and test equipment to demonstrate compliance with the requirements of this standard

[A2] 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. [A2]

A2 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, 11, 13, Annex B, Annex C, Annex E	1.1.3	This relevant EHSR is addressed in this Standard
	1.1.4	This relevant EHSR is not addressed in this Standard
11, 26.2 a)	1.1.5	This relevant EHSR is partly addressed in this Standard
6, 6.1.1.2, 6.3, 7.1.1, 11	1.1.6	This relevant EHSR is partly addressed in this Standard
11	1.1.7	This relevant EHSR is addressed in this Standard
7, 7.1.1, 7.1.6, 7.1.8, 7.1.9, 7.1.10, 7.1.12, 7.2, 11	1.2.1	This relevant EHSR is partly addressed in this Standard
4.3.2.4, 6.1.1.2, 11	1.2.2	This relevant EHSR is addressed in this Standard
11, 14, Annex F	1.2.3	This relevant EHSR is addressed in this Standard
11	1.2.4	This relevant EHSR is addressed in this Standard
7.1.5, 7.1.9, 11, 26.3	1.2.5	This relevant EHSR is addressed in this Standard
11, 13.2	1.2.6	This relevant EHSR is partly addressed in this Standard
4.4, 11, 26.2, 26.3 j), Annex E	1.3.1	This relevant EHSR is partly addressed in this Standard
4.2, 4.4, 5.1, 11, 26.3	1.3.2	This relevant EHSR is addressed in this Standard
11	1.3.3	This relevant EHSR is addressed in this Standard
11	1.3.4	This relevant EHSR is addressed in this Standard
4.4, 11	1.3.7	This relevant EHSR is partly addressed in this Standard

Table ZA.2 *(continued)*

Clause(s)/sub-clause(s) of this EN	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
4.4.2, 11, 26.3 f)	1.3.8.1	This relevant EHSR is partly addressed in this Standard
11, 26.2 o)	1.3.8.2	This relevant EHSR is partly addressed in this Standard
	1.3.9	This relevant EHSR is not addressed in this Standard
	1.4.1	This relevant EHSR is not addressed in this Standard
	1.4.2	This relevant EHSR is not addressed in this Standard
4.3.1, 11, 26.3 b)	1.4.3	This relevant EHSR is partly addressed in this Standard
11	1.5.1	This relevant EHSR is addressed in this Standard
11	1.5.2	This relevant EHSR is addressed in this Standard
5.1, 11	1.5.3	This relevant EHSR is addressed in this Standard
4, 5, 11, 13, 26.2, 26.3, Annex E	1.5.4	This relevant EHSR is partly addressed in this Standard
4.3.4, 5.1.2, 11	1.5.5	This relevant EHSR is addressed in this Standard
4, 5, 11, 26.3	1.5.6	This relevant EHSR is addressed in this Standard
9, 11	1.5.8	This relevant EHSR is addressed in this Standard
	1.5.9	This relevant EHSR is not addressed in this Standard
11	1.5.13	This relevant EHSR is addressed in this Standard
11	1.5.14	This relevant EHSR is addressed in this Standard
7.1.8, 7.1.9, 11, 26.3 b), 26.3 g)	1.6.1	This relevant EHSR is partly addressed in this Standard.

Table ZA.2 *(continued)*

Clause(s)/sub-clause(s) of this EN	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
4.3.2, 4.4.2, 11, 26.3	1.6.2	This relevant EHSR is addressed in this Standard
11	1.6.3	This relevant EHSR is addressed in this Standard
4.3.2, 7.1.8, 7.1.9, 11, 26.3 b)	1.6.4	This relevant EHSR is addressed in this Standard
6, 7.1.6, 7.1.10, 7.1.11, 7.1.12, 7.2, 11, 12.1, 26.1,	1.7.1	This relevant EHSR is partly addressed in this Standard
11	1.7.2	This relevant EHSR is partly addressed in this Standard
11, 12	1.7.3	This relevant EHSR is partly addressed in this Standard
11, 26.2, 26.3	1.7.4	This relevant EHSR is partly addressed in this Standard
11	4	This relevant EHSR is partly addressed in this Standard

〈A2〉

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

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[5] EN 866-1:1997, *Biological systems for testing sterilizers and sterilization processes — Part 1: General requirements*

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[8] EN 868-2, *Packaging materials and systems for medical devices which are to be sterilized — Part 2: Sterilization wrap — Requirements and test methods*

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[11] EN 868-6, *Packaging materials and systems for medical devices which are to be sterilized — Part 6: Paper for the manufacture of packs for medical use for sterilization by ethylene oxide or irradiation — Requirements and test methods*

[12] EN 868-7, *Packaging materials and systems for medical devices which are to be sterilized — Part 7: Adhesive coated paper for the manufacture of heat sealable packs for medical use for sterilization by ethylene oxide or irradiation — Requirements and test methods*

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