



BSI Standards Publication

Sterilizers for medical purposes — Small steam sterilizers — Requirements and testing

National foreword

This British Standard is the UK implementation of EN 13060:2025. It supersedes BS EN 13060:2014+A1:2018, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

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

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© The British Standards Institution 2025
Published by BSI Standards Limited 2025

ISBN 978 0 539 23955 3

ICS 11.080.10

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 August 2025.

Amendments/corrigenda issued since publication

Date	Text affected

English Version

Sterilizers for medical purposes - Small steam sterilizers - Requirements and testing

Stérilisateurs à usage médical - Petits stérilisateurs à la
vapeur d'eau - Exigences et essais

Sterilisatoren für medizinische Zwecke - Dampf-Klein-
Sterilisatoren - Anforderungen und Prüfung

This European Standard was approved by CEN on 23 June 2025.

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European foreword

This document (EN 13060:2025) has been prepared by Technical Committee CEN/TC 102 “Sterilizers and associated equipment for processing of medical devices”, 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of an identical text or by endorsement, at the latest by February 2026, and conflicting national standards shall be withdrawn at the latest by February 2026.

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

This document supersedes EN 13060:2014+A1:2018.

In comparison with the previous edition, the following technical modifications have been made:

- the structure of the main text has been widely adopted to the structure of ISO/TS 22421:2021;
- update of normative references;
- update of terms and definitions to align with EN ISO 11139:2018 and EN ISO 11139:2018/A1:2024;
- for requirement on non-condensable gases test, reference is made to EN 285:2015+A1:2021;
- considerations of aspect of standardization in moist heat sterilization to align with EN ISO 17665:2024.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

In this document, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or capability; and
- “must” is used to express an external constraint.

In this document notes are used for giving additional information intended to assist the understanding or use of the text of document. The document shall be usable without the notes.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia,

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Introduction

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

This document provides minimum requirements for small steam sterilizers and associated test methods. Performance is defined by reference to standard test loads. These are used to define a basic minimum performance and are not necessarily related to specific medical devices. It is the responsibility of the user and the manufacturer of the device to be sterilized to determine that any particular cycle is suitable for sterilizing a particular device. The performance tests specified in this document can also be used by the manufacturer of the device to be sterilized to specify the appropriate performance for decontamination processes according to the requirements for information to be given by medical device manufacturers according to EN ISO 17664-1. This will enable users to identify the specific sterilizer performance required to safely process their devices.

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

It is essential that the sterilizer and ancillary equipment is used only for the sterilization of the type of products for which it is designed. The choice of sterilizer, sterilization cycle or quality of services provided can be inappropriate for a particular product. Therefore, the suitability of a sterilization procedure for a particular product is verified by validation, see EN ISO 17665. Conformance with these requirements for development, validation and routine control of sterilization process ensures that the sterilization process is both reliable and reproducible so that predictions can be made, with reasonable confidence, that there is low probability of there being a viable microorganism present on a health care product after sterilization.

1 Scope

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

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

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

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

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

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

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

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

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 285:2015+A1:2021, *Sterilization — Steam sterilizers — Large sterilizers*

EN 556-1:2024, *Sterilization of medical devices — Requirements for medical devices to be designated “STERILE” — Part 1: Requirements for terminally sterilized medical devices*

EN 764-7:2002,¹ *Pressure equipment — Part 7: Safety systems for unfired pressure equipment*

EN 868-2:2025, *Packaging for terminally sterilized medical devices — Part 2: Sterilization wrap — Requirements and test methods*

EN 868-4:2025, *Packaging for terminally sterilized medical devices — Part 4: Paper bags — Requirements and test methods*

EN 868-5:2018, *Packaging for terminally sterilized medical devices — Part 5: Sealable pouches and reels of porous materials and plastic film construction — Requirements and test methods*

EN 10088-1:2023, *Stainless steels — Part 1: List of stainless steels*

¹ This document is impacted by corrigendum EN 764-7:2002/AC:2006.

EN 13445-1:2021, *Unfired pressure vessels — Part 1: General*

EN 13445-2:2021+A1:2023, *Unfired pressure vessels — Part 2: Materials*

EN 13445-3:2021, *Unfired pressure vessels — Part 3: Design*

EN 13445-4:2021+A1:2023, *Unfired pressure vessels — Part 4: Fabrication*

EN 13445-5:2021+A1:2024, *Unfired pressure vessels — Part 5: Inspection and testing*

EN 13445-8:2021, *Unfired pressure vessels — Part 8: Additional requirements for pressure vessels of aluminium and aluminium alloys*

EN 60529:1991,² *Degrees of protection provided by enclosures (IP Code)*

EN 61010-1:2010,³ *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements (IEC 61010-1:2010)*

EN 62366-1:2015,⁴ *Medical devices — Part 1: Application of usability engineering to medical devices*

EN IEC 60751:2022, *Industrial platinum resistance thermometers and platinum temperature sensors (IEC 60751:2022)*

EN IEC 61010-2-040:2021, *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 61010-2-040:2020)*

EN IEC 61326-1:2021, *Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 1: General requirements (IEC 61326-1:2020)*

EN ISO 228-1:2003, *Pipe threads where pressure-tight joints are not made on the threads — Part 1: Dimensions, tolerances and designation (ISO 228-1:2000)*

EN ISO 4017:2022, *Fasteners — Hexagon head screws — Product grades A and B (ISO 4017:2022)*

EN ISO 4126-1:2013,⁵ *Safety devices for protection against excessive pressure — Part 1: Safety valves (ISO 4126-1:2013)*

EN ISO 11138-3:2017, *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2017)*

EN ISO 11140-1:2014, *Sterilization of health care products — Chemical indicators — Part 1: General requirements (ISO 11140-1:2014)*

² This document is impacted by amendment EN 60529:1991/A1:2000 and EN 60529:1991/A2:2013, with corrigendum EN 60529:1991/A2:2013/AC:2019-02, and corrigendum EN 60529:1991/AC:2016-12.

³ This document is impacted by amendment EN 61010-1:2010:2010/A1:2019 and corrigendum EN 61010-1:2010/A1:2019/AC:2019.

⁴ This document is impacted by corrigenda EN 62366-1:2015/AC:2015 and EN 62366-1:2015/AC:2016-09 and amendment EN 62366-1:2015/A1:2020.

⁵ This document is impacted by amendments EN ISO 4126-1:2013/A1:2016 and EN ISO 4126-1:2013/A2:2019.

EN ISO 11140-6:2022, *Sterilization of health care products — Chemical indicators — Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers (ISO 11140-6:2022)*

EN ISO 14971:2019,⁶ *Medical devices — Application of risk management to medical devices (ISO 14971:2019)*

EN ISO 17665:2024, *Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665:2024)*

EN ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

access device

means by which entry to restricted parts of equipment is achieved

Note 1 to entry: This can be by dedicated key, code, or tool.

[SOURCE: EN ISO 11139:2018, 3.4]

3.2

active drain

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

3.3

automatic controller

device that directs the equipment sequentially through required stages of the cycle in response to programmed *cycle parameters*

[SOURCE: EN ISO 11139:2018, 3.18]

3.4

biological indicator

test system containing viable microorganisms providing a specified resistance to a specified *sterilization process*

[SOURCE: EN ISO 11139:2018, 3.29]

⁶ This document is impacted by amendment EN ISO 14971:2019/A11:2021.

3.5 **calibration**

operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

[SOURCE: EN ISO 11139:2018, 3.31]

3.6 **chamber**

part of equipment in which a load is processed

[SOURCE: EN ISO 11139:2018, 3.36]

3.7 **chemical indicator**

test system that reveals change in one or more pre-specified *process variables* based on a chemical or physical change resulting from exposure to a process

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

[SOURCE: EN ISO 11139:2018, 3.43, modified – Note 1 to entry has been added]

3.8 **control**

regulation of variables within specified limits

[SOURCE: EN ISO 11139:2018, 3.63]

3.9 **cycle complete**

message from the automatic controller that the operating cycle has ended successfully

[SOURCE: EN ISO 11139:2018, 3.71]

3.10 **cycle parameter**

value of a *cycle variable* including its tolerance used for *control*, *monitoring*, indication, and recording of an operating cycle

[SOURCE: EN ISO 11139:2018, 3.72]

3.11 **cycle variable**

property used to *control*, monitor, indicate, or record an *operating cycle*

[SOURCE: EN ISO 11139:2018, 3.74]

3.12**double-ended**

having separate doors for loading and unloading in separate areas

[SOURCE: EN ISO 11139:2018, 3.92]

3.13**equilibration time**

<moist heat sterilization> period between the attainment of defined sterilization process parameters at the reference measurement point and the attainment of the specified sterilization process parameters at all points within the load

Note 1 to entry: For the purpose of this document, the process parameter to which this definition refers is temperature.

Note 2 to entry: Independent of the specific load, for the purpose of this document, the allocation of all points is inside the usable chamber space.

[SOURCE: EN ISO 11139:2018, 3.105, modified – Note 1 and 2 to entry have been added]

3.14**equipment maintenance**

combination of all technical and associated administrative actions intended to keep equipment at a state in which it can perform its required function, or restore it to such a state

[SOURCE: EN ISO 11139:2018, 3.106]

3.15**exposure phase**

cycle stage between the introduction of the sterilizing agent or disinfecting agent into the *chamber* and when the agent is removed

Note 1 to entry: Disinfecting agent does not concern steam sterilization. For the purpose of this document the sterilizing agent is moist heat and the exposure phase corresponds to the plateau period which is used in EN 13060.

[SOURCE: EN ISO 11139:2018, 3.111, modified – Note 1 to entry has been added]

3.16**fault**

situation in which one or more of the process or *cycle parameters* is/are outside its/their specified tolerance(s)

[SOURCE: EN ISO 11139:2018, 3.116]

3.17**hazard**

potential source of harm

[SOURCE: EN ISO 11139:2018, 3.130]

3.18**hazardous situation**

circumstance in which people, property, or the environment is/are exposed to one or more *hazards*

[SOURCE: EN ISO 11139:2018, 3.131]

3.19

holding time

<moist heat sterilization> 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 1 to entry: The holding time follows immediately after the equilibration time. The extent of the holding time is related to the sterilization temperature.

Note 2 to entry: Independent of the specific loads, for the purpose of this document, the allocation of all points is inside the usable chamber space.

[SOURCE: EN ISO 11139:2018/A1:2024, 3.133.1, modified – Note 1 and 2 to entry have been added]

3.20

installation test

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

3.21

load

product, equipment, or materials to be processed together within an *operating cycle*

[SOURCE: EN ISO 11139:2018, 3.155]

3.22

load configuration

distribution and orientation of a *load*

[SOURCE: EN ISO 11139:2018, 3.156]

3.23

loading door

means of access through which a *load* is passed into the chamber before processing

[SOURCE: EN ISO 11139:2018, 3.157]

3.24

locked

with the interlock(s) fully engaged

3.25

maximum allowable pressure

PS

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

[SOURCE: EN 764-1:2015+A1:2016, 3.2.87]

3.26

measurement uncertainty

non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

[SOURCE: EN ISO 11139:2018, 3.164]

3.27**measuring chain**

series of elements of a measuring instrument or measuring system, which constitutes the path of the measurement signal from the input (quantity subject to measurement) to the output (the result of the measurement)

[SOURCE: EN ISO 11139:2018, 3.165]

3.28**medical device**

instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, or 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 medical 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 by means of *in vitro* examination of specimens derived from the human body;

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

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions, but not in others include:

- items specifically intended for *cleaning* or sterilization of medical devices;
- pouches, reel goods, sterilization wrap, and reusable containers for packaging of medical devices for sterilization;
- disinfection substances;
- aids for persons with disabilities;
- devices incorporating animal and/or human tissues;
- devices for *in vitro* fertilization or assisted reproduction technologies.

[SOURCE: EN ISO 11139:2018/A1:2024, 3.166]

3.29**microorganism**

entity of microscopic size, encompassing bacteria, fungi, protozoa, and viruses

[SOURCE: EN ISO 11139:2018, 3.176]

3.30

monitoring

continual checking, supervising, critically observing, or determining the status, in order to identify change from the performance level required or expected

[SOURCE: EN ISO 11139:2018, 3.180]

3.31

narrow lumen

hollow device which is beyond the range defined for a simple hollow item, and which is neither solid nor porous

Note 1 to entry: See Annex D.

EXAMPLE Long tubes, mating surfaces, hinged devices.

3.32

national standard

measurement standard recognized by national authority to serve in a state or economy as the basis for assigning quantity values to other measurement standards for the kind of quantity concerned

[SOURCE: ISO/IEC Guide 99:2007, 5.3]

3.33

non-condensable gas

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

3.34

normal operation

use of equipment in accordance with the manufacturer's instructions and with all *process parameters* within the specified tolerances

[SOURCE: EN ISO 11139:2018, 3.185]

3.35

operating cycle

complete set of stages of a process that is carried out, in a specified sequence

Note 1 to entry: Loading and unloading are not part of the operating cycle.

[SOURCE: EN ISO 11139:2018, 3.188]

3.36

operating pressure

fluid pressure occurring during an *operating cycle*

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

[SOURCE: EN ISO 11139:2018, 3.189, modified – Note 1 to entry has been added]

3.37**plateau period**

equilibration time plus the holding time

[SOURCE: EN ISO 11139:2018, 3.195]

3.38**porous**

<sterilizer load> permeable to water, air or other fluids

[SOURCE: EN ISO 11139:2018, 3.197]

3.39**pressure vessel**

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

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

[SOURCE: EN ISO 11139:2018, 3.202]

3.40**process challenge device****PCD**

item providing a defined resistance to a cleaning, disinfection, or-sterilization process and used to assess performance of the process

Note 1 to entry: For the purposes of this document the process challenging device provides defined resistances to a sterilization process.

[SOURCE: EN ISO 11139:2018, 3.205, modified – Note 1 to entry has been added]

3.41**process parameter**

specified value for a *process variable*

Note 1 to entry: The specification for a process includes the process parameters and their tolerances.

[SOURCE: EN ISO 11139:2018, 3.211]

3.42**process variable**

chemical or physical attribute within a *cleaning*, disinfection, packaging, or *sterilization process*, changes in which can alter its effectiveness

Note 1 to entry: For the purposes of this document, process variables are conditions within a sterilization process, changes in which alter microbicidal effectiveness, i.e. exposure time and temperature in the presence of moist heat.

[SOURCE: EN ISO 11139:2018, 3.213, modified — EXAMPLES have been deleted and Note 1 to entry has been added]

3.43

recorder

equipment that *records* and produces a permanent record of information graphically, digitally, or electronically

Note 1 to entry: For the purposes of this document recorders that are state of the art can also provide analogue recordings. This does not contradict their primary classification to produce graphics or digits.

[SOURCE: EN ISO 11139:2018, 3.224, modified – Note 1 to entry has been added]

3.44

reference measurement point

location of the sensor controlling the operating cycle

Note 1 to entry: For the purposes of this document the location controlling the operating cycle contains at least a temperature sensor.

[SOURCE: EN ISO 11139:2018, 3.227, modified – Note 1 to entry has been added]

3.45

risk assessment

overall process comprising a risk analysis and a risk evaluation

[SOURCE: EN ISO 14971:2019, 3.20]

3.46

risk control

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

[SOURCE: EN ISO 14971:2019, 3.21, modified; “in” replaced by “through” and “made and measures” replaced by “reached and protective measures are”]

3.47

saturated steam

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

[SOURCE: EN ISO 11139:2018, 3.241]

3.48

services

supplies from an external source needed for the function of equipment

[SOURCE: EN ISO 11139:2018, 3.252]

3.49**simple hollow item**

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

Note 1 to entry: See Annex A.

EXAMPLE Bowls, receivers.

3.50**small steam sterilizer**

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

3.51**solid**

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

3.52**stage**

<operating cycle> part of an *operating cycle* with a specified function

EXAMPLE Air removal stage, plateau period, drying stage, final air admission stage.

[SOURCE: EN ISO 11139:2018, 3.262]

3.53**sterile**

free from viable *microorganisms*

[SOURCE: EN ISO 11139:2018, 3.271]

3.54**sterile barrier system****SBS**

minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the *sterile* contents at the point of use

[SOURCE: EN ISO 11139:2018, 3.272]

3.55**sterilization**

validated process used to render product free from viable *microorganisms*

Note 1 to entry: In a sterilization process, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

[SOURCE: EN ISO 11139:2018, 3.277]

3.56
sterilization cycle

predetermined sequence of stages performed in a *sterilizer* to achieve product free of viable *microorganisms*

[SOURCE: EN ISO 11139:2018, 3.279]

3.57
sterilization cycle type

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

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

Table 1 — Types of sterilization cycles

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

3.58
sterilization module

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

[SOURCE: EN 285:2015+A1:2021, 3.31]

3.59
sterilization process

series of actions or operations needed to achieve the specified requirements for sterility

Note 1 to entry: This series of actions includes pre-treatment of product (if necessary), exposure under specified conditions to the sterilizing agent, and any necessary post treatment. The sterilization process does not include any cleaning, disinfection, or packaging operations that precede sterilization.

[SOURCE: EN ISO 11139:2018, 3.284]

3.60**sterilization temperature**

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

[SOURCE: EN ISO 11139:2018, 3.286]

3.61**sterilization temperature band**

temperature range the minimum of which is the sterilization temperature

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

[SOURCE: EN ISO 11139:2018, 3.293.1, modified – “temperature band” has been changed to “sterilization temperature band”]

3.62**sterilizer**

equipment designed to achieve *sterilization*

[SOURCE: EN ISO 11139:2018, 3.287]

3.63**sterilizing agent**

physical or chemical entity, or combination of entities, having sufficient microbicidal activity to achieve sterility under specified conditions

[SOURCE: EN ISO 11139:2018, 3.288]

3.64**technical description**

portion of the accompanying information directed to the responsible organization and service personnel that is essential for preparation for the first use and safe use, equipment maintenance or repair as well as transport or storage for the expected lifetime of a *sterilizer*

Note 1 to entry: The technical description may be included in the instructions for use.

[SOURCE: EN ISO 20417:2021, 3.30, modified — “Medical device” has been changed to sterilizer, “processing” has been deleted and Note 2 to entry has been deleted.]

3.65**theoretical steam temperature**

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

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

where

T is the theoretical steam temperature in Kelvin;

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

A is 42,677 6 K;

B is $-3\,892,70\text{ K}$;

C is $-9,486\,54$

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

3.66

type test

technical operation to verify conformity of an equipment type to a standard or specification, and to establish data for reference in subsequent tests

Note 1 to entry: For the purposes of this document, the equipment to which this definition refers is a sterilizer.

[SOURCE: EN ISO 11139:2018, 3.306, modified – Note 1 to entry has been added]

3.67

unloading door

means through which a load is removed from the chamber after processing

[SOURCE: EN ISO 11139:2018, 3.310]

3.68

usable chamber space

specified geometry within the *chamber* that is available to accept the load

Note 1 to entry: The availability to the load implies, that the usable chamber space is not restricted by fixed or mobile parts.

[SOURCE: EN ISO 11139:2018, 3.311, modified – Note 1 to entry has been added]

3.69

validation

confirmation process, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

Note 1 to entry: The objective evidence needed for a validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word “validated” is used to designate the corresponding status.

Note 3 to entry: The use conditions for validation can be real or simulated.

[SOURCE: EN ISO 11139:2018, 3.313]

3.70

verification

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

Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word “verified” is used to designate the corresponding status.

[SOURCE: EN ISO 11139:2018, 3.314]

3.71**water charge**

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

3.72**works test**

series of technical operations performed prior to delivery to demonstrate compliance of a piece of equipment with its specification

[SOURCE: EN ISO 11139:2018, 3.325]

3.73**wrapped**

enclosed within a package (sterile barrier system)

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

4 General**4.1 Product definition**

4.1.1 When demonstrating that a sterilizer type conforms with this document, sterilizers classified as the same type shall have the same intended use with the same sterilizing agent specification. In addition, unless it has been demonstrated that there is no decrease in the performance of an operating cycle, a sterilizer type shall have:

- a) the same number of loading or unloading doors in the same configuration;
- b) all service connections into the sterilizer chamber in the same orientation;
- c) the same control system with all fixed sensors required in this document located in the same position and orientation;
- d) the same pre-set programmes of operating cycle(s) including the same cycle parameters.

NOTE 1 A mirror image of the original orientation does not constitute a new type.

NOTE 2 Where change within the control system does not affect the sequence of stages of the sterilization cycle, and the parameters limiting the cycle performance, or the safety attributes, such a change does not constitute a new type.

Conformance is demonstrated by inspection of the technical documentation.

4.1.2 If all other design aspects remain the same, the following variations shall not constitute a new sterilizer type:

- a) height of the sterilizer chamber above the floor;
- b) differences in the dimensions of the sterilizer chamber not greater than $\pm 10\%$ of the dimensions with congruent sterilizer chamber shapes;
- c) prolonging the duration of the exposure phase (holding time or plateau period) of an operating cycle having the same sterilization temperature and the same air removal stage;

NOTE Additional regulatory requirements can apply to prolonging the exposure phase (holding time or plateau period).

- d) prolonging cooling or drying after the exposure phase (holding time or plateau period);
- e) any change of the design or provenance of equipment, including chamber furniture, providing there is available documented evidence to show there is no decrease in the safety or performance of the sterilizer which can affect conformance with this document.

Conformance is demonstrated by inspection of the technical documentation.

4.2 Equipment development

The design and development process are critical elements in product realization of a sterilizer. To ensure the consistent implementation of the requirements specified in this document, the necessary processes shall be established, implemented and maintained. Processes of particular importance in relation to the design and development of a sterilizer include but are not limited to:

- risk management and usability engineering;
- control of documentation, including records;
- assignment of responsibility;
- provision of adequate resources, including competent human resources and infrastructure;
- control of product, including services, provided by external parties;
- calibration of instrumentation.

NOTE 1 EN ISO 13485 covers all stages of the lifecycle of medical devices in the context of quality management systems for regulatory purposes. National or regional regulatory requirements for the provision of health care product can require the implementation of a full quality management system and the assessment of that system by a recognized conformity assessment body.

NOTE 2 EN ISO 12100 provides information on risk management of machinery.

NOTE 3 EN 62304 provides information on software lifecycle processes.

NOTE 4 EN 62366-1 provides information on usability engineering.

4.3 Calibration

4.3.1 Instrumentation on the sterilizer and instruments used for test purposes shall be calibrated. The system(s) for calibration of instrumentation shall provide metrological traceability to a primary standard or national standard with a known level of measurement uncertainty.

NOTE National calibration standards are often mutually recognized and traceable to international standards with recognized fixed-points.

Conformance is demonstrated by inspection of the technical documentation.

4.3.2 Means shall be provided to permit connection of reference instruments for the calibration of instrumentation (see 5.5).

Conformance is demonstrated by inspection.

5 Equipment design and construction

5.1 Safety and security

5.1.1 General requirements

5.1.1.1 The sterilizer shall conform to the following requirements of EN 61010-1:2010 and EN IEC 61010-2-040:2021, if applicable:

- a) For the protection against electric shock sterilizers shall comply with EN IEC 61010-2-040:2021, Clause 4 and Clause 6, Annex A, Annex B, Annex C, Annex D, Annex F, Annex H, Annex K.

NOTE 1 EN IEC 61010-2-040 supplements EN 61010-1. All requirements of EN 61010-1 are included by reference and supplemented or modified for a specific application to sterilizers or washer-disinfectors.

- b) For the protection against mechanical hazards and hazards related to mechanical functions sterilizers shall comply with EN IEC 61010-2-040:2021, Clause 4 and Clause 7.
- c) For the protection against hazards due to mechanical resistance to shock and impact sterilizers shall comply with EN IEC 61010-2-040:2021, Clause 4 (except 4.4) and Clause 8.
- d) For the protection against the spread of fire sterilizers shall comply with EN IEC 61010-2-040:2021, Clause 4 and Clause 9 (except 9.5).
- e) For the protection against hazards in relation to equipment temperature limits and resistance to heat sterilizers shall comply with EN IEC 61010-2-040:2021, Clause 4 and Clause 10.
- f) For the protection against hazards from fluids sterilizers shall comply with EN IEC 61010-2-040:2021, Clause 4 and Clause 11.
- g) For the protection against radiation, including laser sources, sterilizers shall comply with EN IEC 61010-2-040:2021, Clause 4, 12.1, 12.3 and 12.6.
- h) For the protection against liberated gases, substances, explosion and implosion sterilizers shall comply with EN IEC 61010-2-040:2021 Clause 4, 13.1.102, 13.2 and 13.101.6.
- i) For the protection against hazards related to components sterilizers shall comply with EN IEC 61010-2-040:2021, Clause 4 and Clause 14.

NOTE 2 Additional guidance is given in EN ISO 12100.

Conformance is demonstrated in accordance with EN IEC 61010-2-040:2021.

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

5.1.1.3 Sterilizers shall incorporate means of protection from unauthorized access that can interfere with its performance or create a hazardous situation.

5.1.1.4 If the sterilizer provides a connection to an IT environment or network, means shall be provided to prevent access or interaction:

- a) between that environment or network and the sterilizer that interferes with the sterilizer performance or creates a hazardous situation;
- b) between the sterilizer and that environment or network protocol(s) that interferes with the specified performance of the environment or network.

NOTE See EN IEC 80001-1, EN ISO/IEC 27001, EN ISO/IEC 27002, UL 2900-1, ISO/IEC 21823-1 and EN IEC 80001-1 for more information on roles, responsibilities and activities that are necessary for risk management of IT-networks incorporating medical devices to address safety, effectiveness and data and system security. EN ISO/IEC 27001 specifies the requirements for establishing, implementing, maintaining and continually improving an information security management system and EN ISO/IEC 27002 gives guidelines for organizational information security standards and information security management practices. UL 2900-1 applies to network-connectable products that need to be evaluated and tested for vulnerabilities, software weaknesses and malware. ISO/IEC 21823-1 provides an overview of interoperability as it applies to Internet of Things systems and a framework for interoperability for such systems.

Conformance is demonstrated by inspection of the technical documentation.

5.1.2 Electromagnetic interference

Sterilizers shall conform to EN IEC 61326-1:2021 regarding immunity to electromagnetic interference.

The immunity performance criteria selected shall ensure that sterilizer performance as specified by Clause 10 of this document is met when exposed to the applicable disturbance phenomena of EN IEC 61326-1:2021, Table 1.

NOTE More information regarding electromagnetic emissions is provided in 8.1.

Conformance is demonstrated in accordance with EN IEC 61326-1:2021.

5.1.3 Risk control and usability

5.1.3.1 Risk assessment and risk control for sterilizer design and software shall be performed following the procedures and requirements given in EN ISO 14971:2019. Specific requirements and results shall be established and documented.

For products designed and placed on the market prior to publication of this document, other standards may apply instead of EN ISO 14971:2019.

NOTE EN ISO 12100 can provide further information.

Conformance is demonstrated by inspection of the technical documentation.

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

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

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

5.1.3.4 Usability engineering in accordance with EN 62366-1:2015 shall be used to identify known or foreseeable hazards and hazardous situation, to improve the usability of the equipment and to identify related risks.

5.2 Chamber

5.2.1 Dimensions

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

5.2.1.2 The internal dimensions of the chamber shall be specified by reference to the principle dimensions at specified positions, measured in millimetres.

a) For cylindrical horizontal or cylindrical vertical chambers:

- 1) diameter;
- 2) depth.

b) For rectangular parallelepiped chambers:

- 1) width;
- 2) height;
- 3) depth.

c) For other configurations the chamber shall be specified in analogy to a) or b).

Conformance is demonstrated by inspection of the technical documentation.

5.2.1.3 The usable chamber space shall be specified. The following dimensions shall be specified in millimetres.

a) For cylindrical horizontal or cylindrical vertical usable chamber space:

- 1) diameter;
- 2) depth.

b) For rectangular parallelepiped usable chamber space:

- 1) width;
- 2) height;
- 3) depth.

c) for other configurations the chamber shall be specified in analogy to a) or b).

Conformance is demonstrated by inspection of the technical documentation.

5.2.2 Doors

The chamber shall be provided with one or two doors.

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

Conformance is demonstrated by inspection.

5.2.3 Chamber integrity

If a leak into the chamber or connected relevant pipework can create a hazardous situation or affect the intended function or performance of the equipment or the process, means shall be provided to conduct an air leakage test capable of detecting that leak (see D.2).

Conformance is demonstrated by inspection of the technical documentation.

5.2.4 Pressure vessels

5.2.4.1 Pressure vessels shall comply with EN 13445-1:2021, EN 13445-2:2021+A1:2023, EN 13445-3:2021, EN 13445-4:2021+A1:2023, EN 13445-5:2021+A1:2024, EN 13445-8:2021 that are applicable.

NOTE Other pressure equipment standards such as EN 14222 can apply.

5.2.4.2 For the protection against hazards in relation to safety for unfired pressure equipment and assemblies, sterilizers shall comply with all parts that are applicable of EN 13445-1:2021, EN 13445-2:2021+A1:2023, EN 13445-3:2021, EN 13445-4:2021+A1:2023, EN 13445-5:2021+A1:2024, EN 13445-8:2021 and EN 764-7:2002.

NOTE Additional guidance is given in EN ISO 12100.

Conformance is demonstrated by inspection of the technical documentation.

5.2.4.3 For sterilizers excluded from Pressure Equipment Directive 2014/68/EU, the safety devices, or their relevant components shall:

- a) be either fail-safe, have redundancy or be self-diagnostic;
- b) be independent from other safety functions, unless the other safety functions are proven not to be affected by these safety devices or their relevant functions;
- c) have a protection level of at least IP 31 in accordance with EN 60529:1991;
- d) have safety valves complying with EN ISO 4126-1:2013;
- e) have safety valves for steam and compressed air provided with means for manual testing, which shall be arranged such that the valves can be lifted off their seats when operating under pressure.

When the Pressure Equipment Directive 2014/68/EU is not applicable, national regulations can apply.

5.2.5 Uniformity of conditions

The conditions within the usable chamber space shall be maintained within the tolerances specified for the sterilization cycle.

Conformance is demonstrated in accordance with 10.3, 10.7 and if applicable in accordance with 10.2, 10.6.

5.2.6 Ancillary equipment and components

5.2.6.1 Means shall be provided to insert and remove the load from the chamber and maintain the load in its intended position within the usable chamber space.

5.2.6.2 The sterilizer shall be equipped with chamber furniture equivalent to the type used in the type test.

NOTE Further guidance on accessories is given in Annex G.

Conformance is demonstrated by inspection of the technical documentation.

5.2.6.3 The air admitted to return the sterilizer chamber to atmospheric pressure after a vacuum drying stage shall be admitted through a filter which shall:

- a) be constructed from materials compatible with steam sterilization;
- b) be readily accessible;
- c) be protected from any influence that can impair its proper function;
- d) retain not less than 99,5 % of particles greater than 0,30 µm.

Conformance is demonstrated by inspection of the technical documentation.

5.3 Materials

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

- resist the attack of steam and condensate;
- not lead to deterioration of the quality of the steam.

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

NOTE 1 For further information see Annex I.

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.

Conformity is checked by inspection of the technical documentation.

5.4 Interlocks

5.4.1 For the protection by interlocks sterilizers shall comply with EN IEC 61010-2-040:2021, Clause 4, 7.101 and Clause 15.

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

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

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

5.4.3 It shall not be possible to open a sterilizer door(s) during an operating cycle, except through special intervention that will lead to a “fault” indication.

5.4.4 Indication of cycle complete shall be cancelled when a door is opened.

5.4.5 In addition to 5.4.1 to 5.4.4, for double-ended sterilizers:

- a) at the successful completion of a sterilization cycle, the loading door shall remain locked until the unloading door has been opened, closed and locked again;
- b) for test purposes, a test load may be removed through the loading door using an access device;

- c) for test purposes, an access device may be required to open either the loading or the unloading door;
- d) if a fault is indicated, both doors shall remain locked, and opening of a door shall be allowed only after the end of a suitable recovery procedure (see 5.7.4 and 6.5.2.4) or an equipment maintenance action by use of an access device;
- e) for equipment maintenance purposes, it shall be possible for both doors to be open at the same time using an access device (see also 5.7.5);
- f) it shall only be possible to open the unloading door when cycle complete is indicated.

Conformance with the requirements of 5.4 is demonstrated as applicable in accordance with EN IEC 61010-2-040:2021, by visual inspection, application testing or inspection of the technical documentation.

5.5 Test connections

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

The test connection(s) shall have an internal pipe thread conforming to G1/4 in accordance with EN ISO 228-1:2003.

Conformance is demonstrated by inspection of the technical documentation.

5.5.2 Test connection(s) shall be at points of easy access to the chamber, but not in pipes for media transport (e.g. steam, air). The test connection(s) shall be clearly marked.

Conformance is demonstrated by inspection of the technical documentation.

5.5.3 The test connection shall provide access into the sterilizer chamber providing it causes no adverse effect on the measurement of the conditions in the sterilizer chamber.

Conformance is demonstrated by inspection of the technical documentation.

5.5.4 If a test connection can be opened and closed without the use of a tool, means shall be provided to prevent opening if conditions inside the equipment can cause a hazardous situation.

NOTE Means can include interlocks, fitting an interlocked cover over the test connection or providing a protective barrier to avoid creation of a hazardous situation.

Conformance is demonstrated by inspection.

5.6 Vibration

5.6.1 Vibrations from sterilizers shall be reduced by design, selection of components and devices limiting vibrations, particularly at source. If vibrations can cause a loss of stability of the sterilizer, means shall be provided for suitable fixation.

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

NOTE Vibration from other sources applicable to the intended use of the sterilizer can also be considered.

Conformance is demonstrated by inspection of the technical documentation.

5.7 User interfaces

5.7.1 The control used to start the automatic operating cycle shall be located at the loading side of the sterilizer or in a remote operating facility.

If used, a remote operating facility shall provide at least an equal level of monitoring and safety as operation from the loading side of the sterilizer.

Conformance is demonstrated by inspection of the technical documentation.

5.7.2 If a fault is indicated, or on completion of an operating cycle for test or equipment maintenance purposes, it shall not be possible to open a door until appropriate action is taken (see 6.5.2).

5.7.3 Double-ended sterilizers shall be provided with the indicating devices specified in 6.7.5 and 6.7.6 at both ends of the sterilizer.

Conformance is demonstrated by inspection of the technical documentation.

5.7.4 Means shall be provided for the user to terminate the sterilization cycle without causing a hazardous situation. If a fault results in aborting or terminating an operating cycle in progress, the visual indication of the fault shall continue until the user completes a specified action to clear the indication of the fault. If an operating cycle is interrupted, opening of the sterilizer door shall require the use of an access device.

Conformance is demonstrated by inspection of the technical documentation.

5.7.5 Means shall be provided to permit operation of the sterilizer for equipment maintenance, test purposes and in cases of emergency, without causing a hazardous situation. The activation of any equipment maintenance mode shall be clearly indicated in order to avoid safety features being inactivated during normal operations.

Conformance is demonstrated by inspection.

5.7.6 Indicating, measuring and recording instruments shall be identified as to their function. Instruments and indicating devices specified in 6.7 shall be located where they can be viewed readily by the user under normal operation of the sterilizer. Unless otherwise specified in this document, the required, instruments and gauges shall be readable by normal or corrected vision from a distance of 1 m and with a minimum illumination of (215 ± 15) lx. If an instrument on the sterilizer is adjustable, adjustment shall require the use of an access device.

Conformance is demonstrated by inspection.

5.7.7 When fitted, acoustic signals not associated with a hazardous situation shall be time-limited to 30 s and/or it shall be possible to interrupt them.

Conformance is demonstrated by inspection.

5.8 Transport

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

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

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

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

Conformance of 5.8 is demonstrated by inspection of the technical documentation.

6 Indicating, monitoring, controlling and recording

6.1 General

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

The cycle parameters including their tolerances for controlling, monitoring, recording and indicating the operating cycle(s) shall be established and incorporated into pre-set programme(s) of the sterilizer.

NOTE A pre-set programme can have a range of cycle parameters selectable by the end user.

Conformance is demonstrated by inspection of the technical documentation.

6.2 Automatic control

6.2.1 The sterilizer shall be provided with an automatic controller. The automatic controller shall be programmed with the pre-set cycle parameters for each stage of the sterilization cycle. It shall not be possible to change cycle parameters during a cycle. The pre-set cycle parameters shall only be adjustable by use of an access device. The automatic controller shall be capable of monitoring the specified pre-set cycle parameters.

6.2.2 The sterilizer shall operate with pre-set programmes permanently stored in the automatic controller. Means shall be provided to ensure that a failure in a control function does not lead to a failure in recording of process parameters such that an ineffective process appears effective. This may be achieved either by the use of independent systems for control and recording, by a control and monitoring system, or by a cross-check between control and recording that identifies any discrepancies and indicates a fault.

NOTE For further information on monitoring systems see Annex E.

Examples of the interrelationship between control and recording are illustrated in the informative Annex H.

Conformance is demonstrated by inspection of the technical documentation.

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

- the switch points of all vacuum and steam pressure pulses;
- the sterilization cycle pressure and temperature; and
- the holding times related to the available sterilization cycles (see 11.2).

6.2.4 The automatic controller shall cause a visual indication that a “fault” has occurred and not cause a hazardous situation, if:

- the values of cycle variables are outside the specified limits;
- a power failure occurs;
- a failure of a service occurs.

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

Conformance is demonstrated by inspection of the technical documentation.

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

NOTE Indicators and indicator systems are specified in EN ISO 11140-6:2022, 4.1, 4.4 and 4.5.

6.2.6 The automatic controller shall be protected against short circuit in components or equipment, which are directly or indirectly connected to the controller.

NOTE For more information see EN 60204-1 or EN 60335-1. Verification can be achieved by assessing conformance with EN 60204-1 or EN 60335-1. EN 60204-1 applies to non-portable electrical, electronic and programmable electronic equipment and systems to machines. EN 60335-1 deals with the safety of electrical appliances for household and similar purposes including appliances not intended for normal household use but which nevertheless can be a source of danger to the public, such as appliances intended to be used by laymen in shops.

Conformance is demonstrated by inspection of the technical documentation.

6.2.7 When a sensor is used for a control function, it shall have a broken sensor protection that fails to safety.

NOTE Failure to safety can be electronic or mechanical.

Conformance is demonstrated by inspection of the technical documentation.

6.2.8 The automatic controller shall be located such that the maximum values of temperature, humidity and any limiting ambient pressure values specified for the automatic controller are not exceeded.

Conformance is demonstrated by inspection of the technical documentation.

6.2.9 Means shall be provided so that if a failure of the automatic controller occurs, the door(s) can be opened without causing a hazardous situation.

Conformance is demonstrated by inspection of the technical documentation.

6.3 Software

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

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

6.3.3 Software parts related to safety of patients, users or any other shall be verified and validated using methods in accordance with the state of art. The methods used in the verification and validation processes shall be selected based on the intended purpose of the software and shall be justified and documented.

NOTE See, for example, the EN 61508 series, EN 62304 and EN IEC 62061. The EN 61508 series applies to safety-related systems when one or more of such systems incorporate electrical or electronic or programmable electronic devices. EN 62304 defines the life cycle requirements for medical device software. EN IEC 62061 specifies and makes recommendations for the design, integration and validation of safety-related electrical, electronic and programmable electronic control systems for machines.

Conformance is demonstrated by inspection of the technical documentation.

6.4 Control and monitoring system

6.4.1 The control and monitoring system shall have separate measuring chains for the measurement of control data and independent data for the monitoring system, if applicable (see 6.4.2, 6.8.1).

NOTE 1 This can consist of measurement chains for temperature and pressure compared to a measurement chain for temperature, within a software module (see Figure E.2).

Independent measurement systems with separate measurement chains for controlling and recording shall be applied to defined cycle variables and process variables (see 6.8.1.3). Separate analogue to digital converters shall be used for the control data and independent data, if applicable (see 6.8.1.4).

NOTE 2 Measurement systems providing a higher level of redundancy can be used.

NOTE 3 Risk analysis identifies which cycle variables or process variables require redundant supervision.

Conformance is demonstrated by inspection of the technical documentation.

6.4.2 If fitted, the monitoring system shall:

- a) compare with a validated cycle any change in pressure and temperature and the period of the cycle during which the change occurs; any change beyond programmed limits shall cause a fault to be indicated;
- b) compare two independent temperature sensors, which may be those associated with the sterilizer chamber temperature indicating instrument and the temperature recorder;
- c) be capable of comparing the theoretical steam temperature with the chamber temperature during the holding time;

NOTE Sterilizer types of an established design, that have been available in the market in conformity to EN 13060:2014+A1:2018 prior to publication of this document, that include a process evaluation (monitoring) system according to EN 13060:2014+A1:2018, 4.4.5.1, capable of comparing the theoretical steam temperature with the chamber temperature during the holding time, can be considered to be compliant with the safety requirements for control and monitoring of the sterilization cycles as required by this document (see Annex E).

- d) have a temperature measuring system accuracy better than or equal to that specified for the chamber temperature indicating instrument;
- e) have a pressure measuring system accuracy better than or equal to that specified for the chamber pressure indicating instrument;
- f) have a time measuring system with an accuracy of $\pm 1\%$ or better;
- g) operate to the specified limits taking into account the monitoring system accuracy;