



BSI Standards Publication

Sterilizers for medical purposes — Low temperature steam and formaldehyde sterilizers — Requirements and testing

National foreword

This British Standard is the UK implementation of EN 14180:2025. It supersedes BS EN 14180:2014, which is withdrawn.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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Exigences et essais

Sterilisatoren für medizinische Zwecke -
Niedertemperatur-Dampf-Formaldehyd-Sterilisatoren
- Anforderungen und Prüfung

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European foreword

This document (EN 14180:2025) 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of an identical text or by endorsement, at the latest by October 2025, and conflicting national standards shall be withdrawn at the latest by October 2025.

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 14180:2014.

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

- structure of the main text has been adapted to the structure of ISO/TS 22421:2021 and harmonized with the current revisions of EN 17180 and EN 1422 in 2024;
- references have been updated, including Table H.1 on Environmental Aspects, and the bibliography;
- some definitions of terms have been added, most definitions have been adapted with reference to EN ISO 11139:2018;
- a separate clause ‘Protective measures’ has been implemented for referencing to individual clauses of EN IEC 61010-2-040:2021;
- a new Annex G ‘Additional information on protective measures’ has been added;
- requirements on the control and monitoring system have been merged into a new clause and informative illustrations including some explanations have been provided in a new Annex F;
- an informative new Annex E ‘Application of Formaldehyde in LTSF-processes’ has been added to explain in some detail the physico-chemical specifics during operation of the sterilizer;
- the specifications provide as a new option a specific cycle for simple items and a ‘simple items test load’ to allow (shorter) cycles for load configurations providing a lower challenge to the sterilization process regarding sterilizing agent penetration, desorption and total mass of the load;
- new Annex ZA has been added to show the Relationship between this European Standard the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered.

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,

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

Introduction

This document provides minimum requirements and test methods for sterilizers working below ambient atmospheric pressure performing a low temperature steam and formaldehyde (LTSF) process.

LTSF sterilizers typically use a mixture of steam and formaldehyde at thermodynamic equilibrium conditions. Sterilization occurs in the condensate layer at the surface of the items to be sterilized.

LTSF sterilizers are primarily used for the sterilization of medical devices in health care facilities but may also be used during the commercial production of medical devices.

LTSF processes are specified by physical parameters and verified using physical, chemical, and microbiological means [42]. The sterilizers operate automatically using pre-set cycles.

The test methods and test equipment given may also be applicable to validation and routine control.

Validation and routine control of sterilization processes are essential to ensure their efficacy. This document does not cover validation and routine control of a LTSF process. Criteria for validation and routine control of LTSF sterilization processes are given in EN ISO 25424.

At the present state of knowledge, LTSF sterilizers should not be assumed to deliver processes effectively inactivating the causative agents of spongiform encephalopathies such as scrapie, Bovine Spongiform Encephalopathy and Creutzfeldt-Jakob Disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents. See also EN ISO 25424:2019, 1.2.1.

Planning and design of products applying to this standard should consider not only technical issues but also the environmental impact from the product during its life cycle. Environmental aspects are addressed in Annex H of this document.

General safety requirements for sterilizers are specified by EN IEC 61010-2-040, amending or modifying respective clauses in EN 61010-1 by references. Further, EN 60204-1 can provide valuable additional options. They are referenced herein, but not repeated. Occupational safety is not addressed in this standard.

1 Scope

1.1 This document specifies requirements and tests for LTSF sterilizers, which use a mixture of low temperature steam and formaldehyde as sterilizing agent, and which are working below ambient pressure only.

These sterilizers are primarily used for the sterilization of heat labile medical devices in health care facilities.

1.2 This document specifies minimum requirements:

- for the performance and design of sterilizers intended to deliver an LTSF process capable of sterilizing medical devices;
- for the equipment and controls of these sterilizers which are needed for operation, control and monitoring of the sterilization processes, and which can be used for validation of the sterilization process.

1.3 This document specifies further test equipment and test procedures used to verify conformance of the equipment design and performance specified by this document.

1.4 This document does not specify requirements and tests for decontamination systems for use in rooms, enclosures, or environmental spaces.

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

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 14222:2021, *Stainless steel steam boilers*

EN 60584-1:2013, *Thermocouples — Part 1: EMF specifications and tolerances (IEC 60584-1:2013)*

EN 61010-1:2010, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements (IEC 61010-1:2010)*²

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

² This document is impacted by amendment EN 61010-1:2010/A1:2019 and corrigendum EN 61010-1:2010/A1:2019/AC:2019.

EN 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to medical devices*³

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 3746:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane (ISO 3746:2010)*

EN ISO 11138-5:2017, *Sterilization of health care products — Biological indicators — Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes (ISO 11138-5:2017)*

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 11607-1:2020, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)*⁴

EN ISO 11607-2:2020, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)*⁵

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

EN ISO 15223-1:2021, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements (ISO 15223-1:2021)*

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

EN ISO 25424:2019, *Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424:2018)*⁷

ISO 8573-1:2010, *Compressed air — Part 1: Contaminants and purity classes*

³ 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.

⁴ This document is impacted by amendments EN 11607-1:2020/A11:2022 and EN 11607-1:2020/A1:2023.

⁵ This document is impacted by amendments EN 11607-2:2020/A11:2022 and EN 11607-2:2020/A1:2023.

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

⁷ This document is impacted by amendment EN ISO 25424:2019/A1:2022.

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 a dedicated key, code or tool.

[SOURCE: EN ISO 11139:2018, 3.4]

3.2

aeration

part of the sterilization cycle during which the sterilizing agent and/or its reaction products desorb from the health care product until predetermined levels are reached

[SOURCE: EN ISO 11139:2018, 3.7]

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]

3.5

chamber

part of equipment in which load is processed

Note 1 to entry: In this document the chamber is the “sterilizer chamber”.

[SOURCE: EN ISO 11139:2018, 3.36, modified – Note 1 to entry added.]

3.6

chamber pre-heating

process that raises the temperature of internal chamber surfaces prior to the commencement of an operating cycle

[SOURCE: EN ISO 11139:2018, 3.37]

3.7

chamber volume

enclosed space of a chamber, including the volume of nozzles to the first connection or weld, and excluding the volume of permanent internal parts

[SOURCE: EN ISO 11139:2018, 3.318.1]

3.8

conditioning

treatment of product prior to the exposure phase to attain a specified temperature, relative humidity, or other process variable throughout the load

[SOURCE: EN ISO 11139:2018, 3.58]

3.9

control

regulation of variables within specified limits

[SOURCE: EN ISO 11139:2018, 3.63]

3.10

cycle complete

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

[SOURCE: EN ISO 11139:2018, 3.71]

3.11

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]

3.12

cycle variable

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

[SOURCE: EN ISO 11139:2018, 3.74]

3.13

desorption

removal of the sterilizing agent from the chamber and the load at the end of the exposure phase

[SOURCE: EN ISO 11139:2018, 3.78]

3.14

development

act of elaborating a specification

[SOURCE: EN ISO 11139:2018, 3.79]

3.15**double-ended**

having separate doors for loading and unloading in separate areas

[SOURCE: EN ISO 11139:2018, 3.92]

3.16**equilibration time**

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

[SOURCE: EN ISO 11139:2018, 3.105]

3.17**establish**

determine by theoretical evaluation and confirm by experimentation

[SOURCE: EN ISO 11139:2018, 3.107]

3.18**exposure stage**

cycle stage between the introduction of the sterilizing agent or disinfecting agent into the chamber and when its microbicidal effect has become negligible

Note 1 to entry: The exposure stage comprises that part of the process for which microbial lethality is claimed.

Note 2 to entry: This can be achieved, for example, by removal or neutralization.

[SOURCE: EN ISO 11139:2018/A1:2024, 3.111, modified – Note 2 to entry added.]

3.19 **F_{BIO} value**

expression of the resistance of a biological indicator calculated as the product of the logarithm of the initial population of microorganisms and the D value

[SOURCE: EN ISO 11139:2018, 3.113.2]

3.20**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]

3.21**filter**

construct of porous material through which a fluid is passed to remove viable and/or non-viable particles

[SOURCE: EN ISO 11139:2018, 3.117]

3.22**hazard**

potential source of harm

[SOURCE: EN ISO 11139:2018, 3.130]

3.23

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]

3.24

holding time

period during which process parameters are maintained, within their specified tolerances

[SOURCE: EN ISO 11139:2018, 3.133]

3.25

indicate

display a value, condition, or stage of process

[SOURCE: EN ISO 11139:2018, 3.139]

3.26

inspection

determination of conformity to specified requirements

Note 1 to entry: If the result of an inspection shows conformity, it can be used for purposes of verification.

Note 2 to entry: The result of an inspection can show conformity or nonconformity or a degree of conformity.

Note 3 to entry: Inspection can be understood as visual inspection and/or application testing.

Note 4 to entry: References to definitions of determination, conformity and specified requirements are removed.

[SOURCE: EN ISO 9000:2015, 3.11.7, modified – Notes 3 and 4 to entry added]

3.27

installation qualification

IQ

process of establishing by objective evidence that all key aspects of the process equipment and ancillary system installation comply with the approved specification

[SOURCE: EN ISO 11139:2018, 3.220.2]

3.28

load

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

[SOURCE: EN ISO 11139:2018, 3.155]

3.29

load configuration

distribution and orientation of a load

[SOURCE: EN ISO 11139:2018, 3.156]

3.30**loading door**

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

[SOURCE: EN ISO 11139:2018, 3.157]

3.31**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]

3.32**medical device**

instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use or software material, or other similar 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 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 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]

3.33

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]

3.34

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]

3.35

operating pressure

fluid pressure occurring during an operating cycle

[SOURCE: EN ISO 11139:2018, 3.189]

3.36

operational qualification

OQ

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

[SOURCE: EN ISO 11139:2018, 3.220.3]

3.37

operator

person using or controlling equipment for its intended purpose

[SOURCE: EN 61010-1:2010, 3.5.11, modified – ‘operating’ replaced by ‘using or controlling’]

3.38

override

system by which an operating cycle can be interrupted or modified as necessary

[SOURCE: EN ISO 11139:2018, 3.191]

3.39

packaging system

combination of a sterile barrier system and protective packaging

[SOURCE: EN ISO 11139:2018, 3.192]

3.40

penetration type test device

PTTD

device for use in type tests to ascertain a minimum sterilizing agent penetration performance during a sterilization cycle

[SOURCE: EN ISO 11139:2018/A1:2024, 3.358]

3.41**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]

3.42**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: In this standard a specific type of PCD is used as penetration type test device (PTTD).

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

3.43**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]

3.44**process variable**

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

EXAMPLE Time, temperature, pressure, concentration, humidity, wavelength.

[SOURCE: EN ISO 11139:2018, 3.213]

3.45**processing**

<preparation of medical devices> activity to prepare a new or used health care product for its intended use

[SOURCE: EN ISO 11139:2018, 3.214]

3.46**product**

tangible result of a process

EXAMPLE Raw material(s), intermediate(s), sub-assembly(ies), health care product(s).

[SOURCE: EN ISO 11139:2018, 3.217]

3.47

product family

group or subgroup of product characterized by similar attributes determined to be equivalent for evaluation and processing purposes

[SOURCE: EN ISO 11139:2018, 3.218]

3.48

record, verb

<data> collect, store, and make accessible

[SOURCE: EN ISO 11139:2018, 3.223]

3.49

recorder

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

[SOURCE: EN ISO 11139:2018, 3.224]

3.50

reference measurement point

location of the sensor controlling the operating cycle

[SOURCE: EN ISO 11139:2018, 3.227]

3.51

requalification

repetition of part or all of validation for the purpose of confirming the continued acceptability of a specified process

[SOURCE: EN ISO 11139:2018, 3.220.5]

3.52

residues challenge device

item used to assess the effectiveness of desorption

[SOURCE: EN ISO 11139:2018, 3.232]

3.53

risk assessment

overall process comprising a risk analysis and a risk evaluation

[SOURCE: EN ISO 14971:2019, 3.20]

3.54

risk control

process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels

[SOURCE: EN ISO 14971:2019, 3.21]

3.55**safety data sheet****SDS**

document specifying the properties of a substance, its potential hazardous effects for humans and the environment, and the precautions necessary to handle and dispose of the substance safely

[SOURCE: EN ISO 11139:2018, 3.239]

3.56**seal**

<packaging> result of joining surfaces together by fusion to form a microbial barrier

[SOURCE: EN ISO 11139:2018, 3.244]

3.57**services**

supplies from an external source needed for the function of equipment

[SOURCE: EN ISO 11139:2018, 3.252]

3.58**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]

3.59**sterilant**

chemical or combination of chemicals used to generate a sterilizing agent

[SOURCE: EN ISO 11139:2018, 3.268]

3.60**sterilant injection**

sterilizing agent injection

introduction of sterilant/sterilizing agent into the evacuated chamber and until the set operating pressure has been attained or the specified quantity of sterilant/sterilizing agent has been delivered

[SOURCE: EN ISO 11139:2018, 3.269]

3.61**sterile**

free from viable microorganisms

Note 1 to entry: For “free from viable microorganisms” see EN 556-1.

[SOURCE: EN ISO 11139:2018, 3.271, modified – Note 1 to entry added.]

3.62

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]

3.63

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]

3.64

sterilization cycle

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

[SOURCE: EN ISO 11139:2018, 3.279]

3.65

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]

3.66

sterilization temperature

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

[SOURCE: EN ISO 11139:2018, 3.286]

3.67

sterilizer

equipment designed to achieve sterilization

[SOURCE: EN ISO 11139:2018, 3.287]

3.68

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]

3.69**temperature band**

range of temperatures expressed as the minimum and the maximum temperatures which prevail during the specified period of a cycle

Note 1 to entry: A modifier to the term may be applied to the term and a note added to cover specific variations in the use of this term in specific standards, e.g. washing temperature band, sterilization temperature band.

[SOURCE: EN ISO 11139:2018, 3.293]

3.70**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

[SOURCE: EN ISO 11139:2018, 3.306]

3.71**unloading door**

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

[SOURCE: EN ISO 11139:2018, 3.310]

3.72**usable chamber space**

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

[SOURCE: EN ISO 11139:2018, 3.311]

3.73**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]

3.74**verification**

confirmation, through the provision of objective evidence, that the 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]

3.75

volume

quantity of three-dimensional space enclosed by a closed surface

[SOURCE: EN ISO 11139:2018, 3.318]

3.76

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]

4 General

4.1 Sterilizer type definition

4.1.1 The “type of sterilizer” concept does establish when design alterations are of a character that requires tests to be repeated. If kept within the same sterilizer type, design variations in an individual sterilizer are not considered to influence the performance and may therefore be exempted from repeated testing. However, in any case a risk evaluation shall be performed for verification.

Conformance is demonstrated by inspection of the technical documentation in accordance with 4.2.2.

4.1.2 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;
- b) all service connections into the chamber in the same orientation;
- c) the same control system with all fixed sensors for measuring the cycle parameters located in the same position and orientation;
- d) the same pre-set programmes of operating cycle(s) including the same cycle parameters.

NOTE Where a 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 in accordance with 4.2.2.

4.1.3 If the 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 and the volume of the sterilizer chamber not greater than $\pm 10\%$ of the dimensions with congruent sterilizer chamber shapes;
- c) a mirror image of the original orientation;

- d) prolonging the duration of the holding time or the exposure stage of an operating cycle;

NOTE 1 Additional regulatory requirements can apply to prolonging the exposure stage.

NOTE 2 Administering additional sterilant during the prolonged period can affect the desorption ability of the sterilizer cycle. In this case repetition of the desorption test described in A.3.5 can be required.

- e) prolonging desorption, cooling or drying after the exposure stage;
- f) any change of the design or provenance of equipment, 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 in accordance with 4.2.2.

4.2 Equipment development

4.2.1 The design and development process is a critical element in product realization of a sterilizer. To ensure the consistent implementation of the requirements specified in this document, the necessary development processes need to 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;
- 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 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.

Conformance is demonstrated by inspection of the technical documentation in accordance with 4.2.2.

4.2.2 Sterilizers, for which conformance with the requirements of this standard is claimed, shall be capable of their conformance to be demonstrated by successfully passing documented test and verification procedures, considering the provisions and respective requirements in this standard. The results of the conformance assessments shall be documented. This documentation is intended to be available for inspection upon justified demand, e.g. for formal registration and conformity assessment purposes. It comprises in parts confidential information that is exceeding those required to be available for the user as specified in Clause 11.

4.2.3 In case of a new type of process is being developed for implementation into a sterilizer [thus becoming a new type, see 4.1.2 d)], an update of the risk analysis (see 5.1.3) shall be performed to ensure that any additional potential risk is considered for the design.

Conformance is demonstrated by inspection of the technical documentation in accordance with 4.2.2.

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 5.2.5).

Conformance is demonstrated by inspection in accordance with 10.1.6.

5 Equipment design and construction

5.1 Safety and security

5.1.1 General

5.1.1.1 Safety of the design shall be based on risk assessment in accordance with 5.1.3. Technical solutions shall consider applicable standards.

NOTE For general design related to safety see EN IEC 61010-2-040:2021.

Conformance is demonstrated by inspection of the assessment reports as documented in accordance with 4.2.2 and 5.1.3.1.

5.1.1.2 The sterilizer or parts thereof can be classified as pressure equipment according to the European Pressure Equipment Directive (PED) [32]. In that case, related harmonized standards should be considered or could even become applicable [see also 5.1.2.2 a) and 5.1.2.3].

NOTE A Directive 2014/68/EU of the European Parliament and of the Council on the harmonization of the laws of the Member States relating to the making available on the market of pressure equipment (PED) [32] was released on 15 May 2014.

5.1.1.3 The sterilizer shall incorporate means of protection from unauthorized access that can interfere with its performance or create a hazardous situation. 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 and ISO/IEC 21823-1. EN IEC 80001-1 defines the 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 instructions for use in accordance with 11.5, and the technical documentation in accordance with 4.2.2.

5.1.2 Protective measures

5.1.2.1 General

Regarding protective measures the respective design of sterilizers shall consider the state of the art, i.e. the applicable standards specifying requirements, and procedures suitable to verify conformance. Further, depending on the type of sterilizer (see Clause 4), the application range and the respective risk classification (see e.g. 5.1.3), different European Directives or national regulations and related harmonized standards can apply.

Conformance is demonstrated by inspection of the technical documentation in accordance with 4.2.2.

5.1.2.2 Specific requirements

Regarding the specific protective measures defined below, the sterilizer shall, besides respective requirements specified elsewhere in this document, comply with the requirements specified in the indicated references to EN IEC 61010-2-040:2021 when tested according to the test methods provided for this purpose. In addition, further related references are provided for information in Annex G and should be taken into account as far as applicable:

- a) For marking, sterilizers shall comply with EN IEC 61010-2-040:2021, 5.1 and 5.2. See also 11.4 of this document.
- b) For the protection against electric shock sterilizers shall comply with EN IEC 61010-2-040:2021, Clause 4 and Clause 6.
- c) 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.
- d) 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.
- e) For the protection against the spread of fire, sterilizers shall comply with EN IEC 61010-2-040:2021, Clause 9 (except 9.5).
- f) For the protection against hazards in relation to equipment temperature and to heat, sterilizers shall comply with EN IEC 61010-2-040:2021, Clause 10.
- g) For the protection against hazards from fluids, sterilizers shall comply with EN IEC 61010-2-040:2021, Clause 11.
- h) For the protection against liberated gases, substances, explosion, and implosion, sterilizers shall comply with EN IEC 61010-2-040:2021, Clause 13.
- i) For the protection against hazards related to components, sterilizers shall comply with EN IEC 61010-2-040:2021, Clause 14.
- j) For the protection against hazards resulting from failures of software, software-controlled devices related to safety of equipment operation or process control shall comply with- EN IEC 61010-2-040:2021, Clause 14.104.

NOTE Safety related software is addressed in 6.2.5 and 6.2.6 of this document.

- k) For the protection by interlocks, sterilizers shall comply with EN IEC 61010-2-040:2021, Clause 15 (see also 5.2.3 of this document).

Conformance of the sterilizer with the stated requirements is demonstrated by successful application of related test procedures provided by the references.

5.1.2.3 For the protection against hazards in relation to safety for pressure equipment and assemblies, if applicable, sterilizers shall comply with EN 764-7:2002, EN 14222:2021, 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 and EN 13445-8:2021 or equivalent specifications.

NOTE Additional guidance is given in EN ISO 12100.

Conformance is demonstrated by assessment in accordance with the Directive 2014/68/EU on pressure equipment [32] and the applicable procedures provided in the referenced standards.

5.1.2.4 If a powered chamber door is fitted, systems shall be provided to permit the removal of persons or objects entrapped by the moving door before the pressure, and force specified in EN IEC 61010-2-040:2021, 7.3.4, are exceeded.

NOTE Reversing the direction of the door movement is a way to achieve this.

Conformance is demonstrated by inspection and inspection of the technical documentation in accordance with 4.2.2.

5.1.2.5 If the internal surfaces of the sterilizer chamber and door are, as part of the process specification, maintained at a temperature which can cause a hazard to operators who could come into contact with the heated surfaces as part of operational activities, then the risk shall be mitigated by warnings to wear protective equipment (e.g. heat proof gloves) within the instruction for use and a symbol at the front(s) of the sterilizer.

Conformance is demonstrated by visual inspection and inspection of the technical documentation in accordance with 4.2.2.

NOTE A suitable symbol is specified in EN 61010-2-040:2015, 10.1.

5.1.2.6 Sterilizers shall conform with EN IEC 61326-1:2021, Clause 6, regarding immunity to electromagnetic interference.

The immunity performance criteria selected shall ensure that sterilizer performance as specified by Clause 6 and Clause 9 of this document is met when exposed to disturbance phenomena of EN IEC 61326-1:2021, 6.2.

NOTE Information regarding electromagnetic emissions are provided in 8.1 of this document.

Conformance is demonstrated in accordance with EN IEC 61326-1:2021, 6.2, Table 1, Table 2 or Table 3, as applicable according to the specified intended use of the sterilizer.

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, Clause 4, Clause 5 and Clause 6. Specific requirements and results shall be established and documented.

Conformance is demonstrated by inspection of the technical documentation in accordance with 4.2.3 as required by EN ISO 14971:2019.

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 helpful information.

Conformance is demonstrated by inspection of the technical documentation in accordance with 5.1.3.1, also in accordance with 11.3, and 11.5.

5.1.3.3 Usability engineering in accordance with EN 62366-1:2015 provides valuable procedures and information to identify known or foreseeable hazards (including reasonably foreseeable misuse), and hazardous situations. The procedures of EN 62366-1:2015 shall be applied to improve the safety and the usability of the equipment and to identify related risks.

Conformance is demonstrated by inspection of the technical documentation in accordance with 5.1.3.1 and the usability engineering file in accordance with EN 62366-1:2015, 4.2.

5.2 Sterilizer chamber

5.2.1 Materials

5.2.1.1 The surfaces of the sterilizer chamber (including, for example, welds) that can come into contact with process chemicals shall be of materials which, under the designed operating conditions, are not impaired by these chemicals.

NOTE 1 When dissimilar metals are used in contact, this can cause contact corrosion and differential expansion.

NOTE 2 EN 13445 series provide further information for sterilizer chamber materials specification.

Conformance is demonstrated by inspection of the technical documentation in accordance with 4.2.2 with reference to EN IEC 61010-2-040:2021, 13.1.103 and 13.2.101.

5.2.1.2 Materials for sterilizer chamber furniture including load supporting systems shall be selected to avoid corrosion and galvanic attack.

Conformance is demonstrated by inspection in accordance with 10.1.6 and inspection of the technical documentation in accordance with 4.2.2.

5.2.2 Dimensions

5.2.2.1 The internal dimensions of the chamber shall be specified by reference to the principal dimensions at specified positions, measured in millimetres:

- a) for rectangular parallelepiped chambers: 000 × 000 × 000 in which:
 - the first three digits give the width of the chamber;
 - the next three digits give the height of the chamber; and
 - the final three digits give the depth of the chamber;
- b) for cylindrical horizontal or cylindrical vertical chambers: 000 × 000 in which:
 - the first three digits give the diameter of the chamber; and
 - the last three digits give the depth of the chamber;
- c) for other configurations the chamber dimensions shall be specified in analogy to a) or b);

d) if any dimension exceeds 999 mm, then four digits shall be used, without a decimal point.

Conformance is demonstrated by inspection of the instructions for use in accordance with 11.5 f).

5.2.2.2 For the usable chamber space the following dimensions shall be specified in millimetres, as applicable:

- a) for rectangular parallelepiped usable chamber spaces: 000 × 000 × 000 in which:
 - the first three digits give the width of the usable chamber space;
 - the next three digits give the height of the usable chamber space; and
 - the final three digits give the depth of the usable chamber space;
- b) for cylindrical horizontal or cylindrical vertical usable chamber spaces: 000 × 000 in which:
 - the first three digits give the diameter of the usable chamber space; and
 - the last three digits give the depth of the usable chamber space;
- c) for other configurations the usable chamber space shall be specified in analogy to a) or b);
- d) if any dimension exceeds 999 mm, then four digits shall be used, without a decimal point.

Conformance is demonstrated by inspection of the technical information to be supplied in accordance with 11.2 f).

5.2.3 Doors and interlocks of the sterilizer chamber

5.2.3.1 Sterilizer chambers shall be provided with one or two doors.

Conformance is demonstrated by inspection in accordance with 10.1.6.

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

Conformance is demonstrated by application testing.

5.2.3.3 Sterilizers shall be equipped with an interlock so that, under conditions of normal operation, the pressure in the chamber cannot be increased or decreased and sterilizing agent cannot enter or escape from the chamber when the door is unlocked or unsealed.

Conformance is demonstrated by inspection of the type test results as documented in accordance with 4.2.2 and the documentation of the risk analysis as documented in accordance with 5.1.3.1.

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

Conformance is demonstrated by application testing.

5.2.3.5 In case of an interrupted cycle (e.g. due to a fault), opening of the sterilizer door e.g. to gain access to the load shall require the use of an access device and a dedicated safety procedure that prevents any hazard.

Conformance is demonstrated by inspection of the technical information and by application testing.

5.2.3.6 The design shall allow easy and safe maintenance of the door seal(s) according to the user instructions for the equipment.

Conformance is demonstrated by inspection of the user instructions and by application testing.

5.2.3.7 Once a sterilization cycle is initiated for routine operation it shall not be possible to open the unloading door until cycle complete is obtained.

Conformance is demonstrated by inspection in accordance with 10.1.6.

5.2.3.8 For operating cycles dedicated for test or maintenance purposes only, the cycle complete indication shall be different from that of a normal sterilization cycle. For double-ended sterilizers such cycle complete indications shall not permit the unloading door to be opened.

Conformance is demonstrated by inspection and application testing.

5.2.3.9 The controls used to start the automatic operating cycle shall be located at the loading side of the sterilizer. To cover specific applications, remote start of the cycle may be possible, if supported by a risk analysis.

Conformance is demonstrated by inspection and application testing.

5.2.3.10 Except for maintenance purposes it shall not be possible to open both doors simultaneously on double-ended sterilizers.

Conformance is demonstrated by application testing.

5.2.3.11 For double-ended sterilizers both ends of the sterilizer shall be fitted with a device to indicate whether the door at that end can be opened.

Conformance is demonstrated by inspection.

5.2.3.12 The indication cycle complete shall be cancelled when a door is opened. For double-ended sterilizers the loading door shall remain locked until the unloading door has been opened, closed and locked again.

Conformance is demonstrated by inspection and application testing.

5.2.4 Temperature control and insulating the sterilizer chamber

5.2.4.1 Inner sterilizer chamber surfaces shall be heated to achieve pre-set temperatures. Initiation of the sterilization cycle shall not be possible until this condition has been fulfilled.

NOTE The chamber doors are part of the chamber.

For demonstration of conformance see A.3.2.1.

5.2.4.2 Where hot outer surfaces of the sterilizer chamber can cause a hazard and to reduce heat transmission to the environment, these surfaces shall be isolated, except where this will interfere the intended function of the sterilizer [see also 5.1.2.2 f)]. This applies as well to dedicated steam supply systems if integral part of the sterilizer.

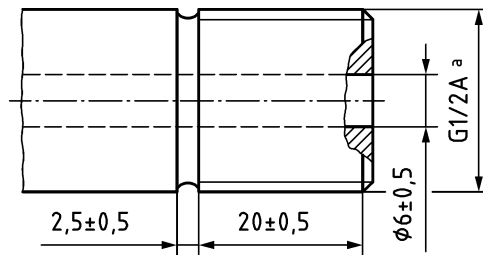
Conformance is demonstrated by inspection.

5.2.5 Test connections

5.2.5.1 The sterilizer chamber shall be provided with a test connection, which is used for the connection of a test pressure measuring instrument. This connection shall be at a point of easy access, but not restricting a pipe for media transport or evacuation and shall terminate in a pipe thread ISO 228 G1/2A in accordance with EN ISO 228-1:2003.

An example is given in Figure 1.

Dimensions in millimetres

**Key**

a pipe thread ISO 228 G1/2A

Figure 1 — Example of the connection for test instruments

The test connection shall be provided with a cap marked PT (Pressure Test) and sealed with a sterilant proof and mechanically resistant O-ring seal or flat seal.

NOTE If national regulations require the calibration of pressure instruments connected to the pressure vessel, test tees and valve cocks with sealing plugs can be required to permit connection of reference instruments.

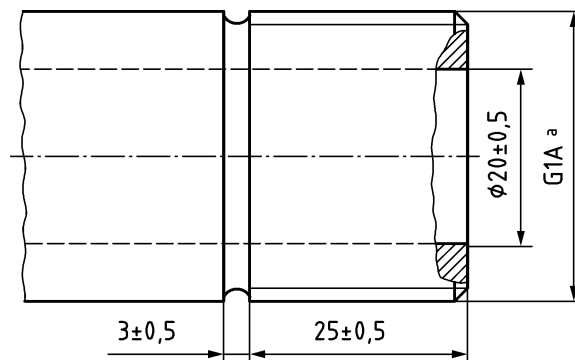
Conformance is demonstrated by inspection.

5.2.5.2 The sterilizer chamber shall be provided with a straight entry connection to allow flexible cords passing through to the internal temperature probes. An example is given in Figure 2. This connection shall be at a point of easy access.

The connection shall be provided with a cap marked TT (Temperature Test) and sealed with a sterilant proof and mechanically resistant O-ring seal or flat seal.

Conformance is demonstrated by inspection.

Dimensions in millimetres

**Key**

a pipe thread ISO 228 G1A

Figure 2 — Example of thermometry entry connection

5.2.5.3 The test connections for pressure and temperature measurement may be provided as entry ports combining both threads (inside/outside), or as accessory to be attached to a single-entry port of the chamber.

Conformance is demonstrated by inspection in accordance with 10.1.6 and inspection of the technical documentation in accordance with 4.2.2.

5.3 Further functional components

5.3.1 Pipework and fittings

5.3.1.1 Pipework and fittings (including e.g. seals) which can get into contact with process chemicals shall be of materials which, under the designed operating conditions, are not impaired by these chemicals. They shall not release any substances known to be toxic in such quantities that can create a health or environmental hazard.

Conformance is demonstrated by inspection of the technical documentation in accordance with EN IEC 61010-2-040:2021, 13.1.103.4, see also Annex G f).

5.3.1.2 Connections for water and steam supply and drainage shall be provided with means to prevent the ingress of particles which can affect the performance of a sterilizer.

NOTE For connections to potable water supply and draining, national or local regulations could apply.

Conformance is demonstrated by inspection of the technical documentation in accordance with 4.2.2.

5.3.1.3 Pipework shall be designed to prevent accumulation of condensate.

Conformance is demonstrated by inspection.

5.3.1.4 Insulation is a way to avoid heat loss or condensation for all pipework carrying media, except where this will interfere with the function of the sterilizer.

Conformance is demonstrated by inspection.

5.3.1.5 All control valves in the pipework shall be marked with permanent identification in relation to their functions.

Conformance is demonstrated by inspection and inspection of the technical documentation in accordance with 4.2.2.

5.3.2 Vaporizer

5.3.2.1 If a vaporizer is part of the sterilizer and can be disconnected from the feed to the chamber, means shall be provided to give protection from accidental hazardous effluent of fluids to the environment.

Conformance is demonstrated by inspection and by inspection of the technical documentation in accordance with EN IEC 61010-2-040:2021, 11.101 and 13.1.

5.3.2.2 Means shall be provided to prevent any excessive temperature and pressure which can create hazards.

NOTE Pressure devices are regulated by the Pressure Equipment Directive 2014/68/EU [32]. EN 14222 can apply.

Conformance is demonstrated by inspection of the technical documentation in accordance with EN IEC 61010-2-040:2021, 11.7 and 14.3.

5.3.3 Evacuation system

5.3.3.1 Sterilizers shall be provided with a vacuum system to remove air, water and formaldehyde. The lowest absolute pressure needed to comply with the requirements for operating cycle control in accordance with A.3.4 shall be specified (see also 6.8 and 10.2.1.4).

NOTE Vacuum systems mostly operate by means of water and energy. Optimization of the use of water can achieve a balance between the use of resources and diluting of formaldehyde into concentrations harmless to environment (see also Annex H).

Conformance is demonstrated by passing the pressure profile tests in accordance with A.3.4.

5.3.3.2 The sterilizer shall be provided with a means for leak testing which shall include the sterilizer chamber and all relevant connected pipework and fittings. Requirements on leak testing are given in 6.8.2.

5.3.4 Aeration system

When the sterilizer chamber is ventilated during the cycle for the purpose of desorption and to release the vacuum at the end of the process, microbial recontamination of the sterilization load shall be prevented. Requirements for admitting air or inert gases to the chamber are specified in 7.10.

5.3.5 Framework and panelling

5.3.5.1 If the sides of the sterilizer need not to be accessible for normal operation, they shall be enclosed with panelling.

NOTE Side panelling is not required for sterilizers designed to be recessed into existing walls or other installations, providing continuous joint with the sterilizer front panelling.

5.3.5.2 Removal or opening of panel used as physical barrier to provide protection (guard) shall require the use of an access device.

5.3.5.3 The panelling shall be long-term corrosion resistant. Instructions for cleaning of the panelling shall be provided.

NOTE Ventilation openings can be provided in the panelling.

5.3.5.4 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.

Fixings for these panels shall remain attached to either the panels or to the body of the sterilizer when panels are removed.

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

NOTE Further information on access are also included in EN IEC 61010-2-040:2021, 7.3 and 7.109.

5.3.5.5 Conformance of the equipment with the requirements in 5.3.5 is demonstrated as applicable by visual inspection and inspection of the technical documentation in accordance with 5.1.2.2 c), see also Annex G c).

5.4 Vibration

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.

NOTE Guidance to reduce vibration at source is provided in EN ISO 12100:2010, 6.2.2.2, 6.2.3, 6.2.6 and 6.3.4.3.

Conformance is demonstrated by inspection in accordance with 10.1.6 and inspection of the technical documentation in accordance with 5.1.2.2 c), see also Annex G c).

5.5 Ancillary equipment and components

5.5.1 If required for ergonomic reasons, 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. EN IEC 61010-2-040:2021, 7.5.101 provides additional requirements on load transfer into and out of the chamber.

Conformance is demonstrated by inspection and inspection of the technical documentation in accordance with 4.2.2.

5.5.2 If the sterilizer is intended to be connected to dedicated ancillary equipment like a printer, these combinations shall not cause any hazard or detrimental effect to the performance of the sterilizer.

Conformance of the mutual compatibility of both systems shall be verified and documented as specified in 4.2.1, 5.1.3 and 11.5 k), see also 5.1.3.1.

5.6 Transport

5.6.1 Where the weight, size or shape of the sterilizer or its various component parts prevents them from being moved by hand, the sterilizer, or each component part must 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.

5.6.2 The sterilizer, its components, and dedicated consumables (if applicable) shall be packed for transportation and storage in a way that their performance characteristics are maintained.

5.6.3 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.

5.6.4 Conformance of the equipment with the requirements in 5.6.1 to 5.6.3 is demonstrated by inspection in accordance with 10.1.6 and inspection of the technical documentation in accordance with 4.2.2.

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.

Conformance is demonstrated by inspection in accordance with 10.1.6.

5.7.2 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 in accordance with 4.2.2.

5.7.3 Sterilizers shall be equipped with indicating devices to provide the indications specified in 6.6.

Conformance is demonstrated by inspection of the technical documentation in accordance with 4.2.2.

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 (see also 6.4).

Conformance is demonstrated by inspection of the instructions for use in accordance with 11.5 q).

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 service mode shall be clearly indicated to avoid safety features being inactivated during normal operations.

Conformance is demonstrated as applicable by inspection in accordance with 10.1.6 and inspection of the technical documentation in accordance with 11.5 r) and 11.6.2, also 4.2.2.

5.7.6 Indicating, measuring, and recording instruments shall be identified as to their function. Instruments and indicating devices shall be located where they can be viewed readily by the user under normal operation of the sterilizer.

Conformance is demonstrated by inspection in accordance with 6.6, 6.7 and 10.1.6.

5.7.7 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 a special tool, key or code.

Conformance is demonstrated by inspection.

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

Conformance is demonstrated by inspection and application testing.

6 Indicating, monitoring, controlling, and recording devices

6.1 Automatic controller

6.1.1 The sterilizer shall be operated by an automatic controller which is part of a system comprising in addition different subunits, e.g. measuring chains, instrumentation, timers and interfaces (see illustrations in Annex F).

Conformance is demonstrated by inspection of the technical documentation in accordance with 4.2.2.

6.1.2 The sterilizer shall operate with pre-set programmes permanently stored in the automatic controller. These shall include one or more pre-set operating cycles.

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

Conformance is demonstrated by inspection of the technical documentation in accordance with 11.2 a) and 11.5 c), see also 4.2.2.

6.1.3 The intended use of the operating cycles and their parameters for control, monitoring, recording and indication shall be specified.

NOTE Automatic loading and unloading can be carried out before the start and after the end of an operating cycle.

Conformance is demonstrated by inspection of the technical documentation and by successful type tests in accordance with Annex A.

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

6.1.5 The automatic controller shall have status indicators for each digital input and output.

NOTE This can be located within the control cabinet.

Conformance is demonstrated by inspection in accordance with 10.1.6.

6.1.6 The automatic controller shall be located such that the maximum and minimum values of temperature, humidity and pressure values specified for operation of the automatic controller are not exceeded.

Conformance is demonstrated by inspection of the technical documentation in accordance with 4.2.2 and the results of type testing in accordance with Annex A.

6.2 Automatic control

6.2.1 The pre-set programmes of the automatic controller shall allow control, indication, monitoring and recording of the sterilizer operation to ensure that the pre-set programmes and their parameters perform safely and reproducibly within specified tolerances as intended and can be verified.

Conformance is demonstrated by inspection of the technical documentation in accordance with 4.2.2, and the results of type testing in accordance with Annex A.

6.2.2 Means shall be provided to ensure that a failure in a control function does not lead to a failure in recording of process and cycle variables such that an ineffective process appears effective. This can be achieved either by the use of independent systems for control and recording, or by a cross-check between control and recording that identifies any deviations of process or cycle parameters outside their specified measurement tolerances and indicates a fault.

NOTE Examples of concepts for control and monitoring systems and the interrelationship between control and recording are discussed and illustrated in Annex F.

Conformance is demonstrated by inspection of the technical documentation in accordance with 4.2.2, considering the concepts provided with Annex F.

6.2.3 The automatic controller shall not cause a hazardous situation, if:

- a) the values of cycle parameters are outside the specified limits;
- b) a power failure occurs;
- c) a failure of another utility occurs.

Conformance is demonstrated by inspection of the technical documentation and the results of type testing in accordance with Annex A.

6.2.4 Software for automatic controllers shall be demonstrated to function as intended. The classification of software with respect to safety shall be established through risk assessment.

Conformance is demonstrated by inspection of the results of the software verification and the risk analysis as documented in accordance with 5.1.3.1.

6.2.5 Safety related software, including software for monitoring, control and recorders shall be verified and validated according to its classification. The methods used in the verification processes shall be selected based on the intended purpose of the software. The methods shall be justified and specified.

NOTE Regarding software requirements, the EN 61508 series, EN 62304 and EN IEC 62061 can provide valuable support.

Conformance is demonstrated by inspection of the technical documentation in accordance with 4.2.2 with reference to the software validation documentation and considering the references in the Note.

6.2.6 Means shall be provided so that if a failure of the automatic controller occurs, the sterilizer shall be brought to a condition that presents no hazard to the operator, any ancillary equipment, or the operating environment, considering formaldehyde being used during the process. Opening of the chamber door(s) shall not cause a hazardous situation and shall require the use of an access device (see also 5.2.3.5).

Conformance is demonstrated by inspection of the instructions for use in accordance with 11.5 q) and the documentation of the risk analysis as documented in accordance with 5.1.3.1.

6.2.7 For sensors for indicating or recording purposes, means shall be provided to indicate a sensor failure.

Conformance is demonstrated by inspection of the technical documentation in accordance with 4.2.2.

6.2.8 When a sensor is used for a control function, it shall have broken sensor indication that causes the system to fail safe.

Conformance is demonstrated by inspection of the technical documentation in accordance with 4.2.2.

6.2.9 Programming the automatic controller and any change of the pre-set programme or its parameters shall require the use of an access device and shall be documented.

Conformance is demonstrated by inspection of the technical documentation in accordance with 4.2.2.

6.2.10 It shall not be possible to adjust any process or cycle parameter during the progress of a sterilization cycle.

Conformance is demonstrated by application testing and inspection of the technical documentation (see also 4.2.2).

6.2.11 Access for change of any controller function shall only be possible by use of an access device.

Conformance is demonstrated by inspection of the information to be provided in accordance with 11.6.3 and the technical documentation in accordance with 4.2.2.

6.2.12 For maintenance, test purposes failure analysis and in cases of emergency, means shall be provided to permit manually controlled progression of the automatic controller using an access device.

NOTE Additional information regarding intervention safety and environmental aspects is given in EN IEC 61010-2-040:2021 (see e.g. 13.1.101, 13.1.102, 13.1.01, 14.103 and 14.104).

Conformance is demonstrated by inspection of the information to be provided in accordance with 11.6.3 and the technical documentation in accordance with 4.2.2.