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BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000

Fax: +44 (0)20 8996 7400

www.bsigroup.com

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Responsible Committee Secretary: Ms Helena Barrell (BSI)

Direct tel:

E-mail: helena.barrell@bsigroup.com

Full document details: 25/30508968 DC

Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

English Version

Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods

Stérilisateurs à usage médical - Stérilisateurs à l'oxyde
d'éthylène - Exigences et méthodes d'essai

Sterilisatoren für medizinische Zwecke - Ethylenoxid-
Sterilisatoren - Anforderungen und Prüfverfahren

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 102.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.



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

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European foreword

This document (prEN 1422:2025) 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 document is currently submitted to the CEN Enquiry.

This document will supersede EN 1422:2014.

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 14180;
- references have been updated, including Table E.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/A1:2024;
- 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.

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. The document is usable without the notes.

Introduction

This document provides minimum requirements and test methods for sterilizers performing a low temperature ethylene oxide (EO) sterilization process.

Ethylene oxide (EO) sterilizers employ EO gas as the sterilant, either as a pure gas or in admixture with other gases (e.g. carbon dioxide). When used as a pure gas the gas exposure stage is usually carried out at sub-atmospheric pressures. When used as an admixture the gas exposure stage is usually carried out at super-atmospheric pressures. Ethylene oxide sterilization processes are primarily used for the sterilization of heat labile products at temperatures less than 60 °C.

EO is a highly reactive chemical which can present a toxicity, flammability or explosive hazard if incorrectly handled (see Annex E).

The EO sterilizer specified in this document can be used for medical, dental, pharmaceutical, veterinary, industrial or other related purposes in health care facilities or industrial settings.

The equipment related tests described in this document are reference tests intended for use in demonstrating conformity with the performance requirements specified in this document. They may be used in type tests, works tests, in validation and re-validation tests, or in periodic and routine tests carried out by the user. Validation and routine control of sterilization processes are essential to ensure their efficacy. This document does not cover validation and routine control of EO sterilization processes. Such activities are covered in EN ISO 11135:2014.

EO 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 11135:2014, 1.2.

Planning and design of sterilizers complying with this document should consider not only technical issues but also the environmental impact from the use of the sterilizer during its life cycle. Environmental aspects are addressed in Annex E of this document.

By performing tests concurrently and/or in a logical succession, the total number of tests and consumable test equipment disposals is reduced. As a result, the burden on the environment can be reduced (see also Annex E).

This document is not intended as a checklist for the suitability of an existing EO sterilizer when assessing compliance with EN ISO 11135:2014. This standard is not intended to be applied retrospectively.

This document does not cover analytical methods for determining levels of residual EO and/or its reaction products. Analytical methods for determining levels of residual EO and/or its reaction products are addressed in ISO 10993-7:2008.

General equipment safety requirements are specified in EN 61010-1:2010, EN IEC 61010-2-040:2021 and EN 60204-1:2018 and can provide valuable information on design options. They are referenced herein, but not repeated.

Occupational safety is not addressed in this document.

1 Scope

1.1 This document specifies the requirements and the relevant tests for automatically controlled sterilizers employing ethylene oxide (EO) gas as the sterilant, either as a pure gas or a mixture with other gases, being used for the sterilization of medical devices and their accessories.

1.2 This document specifies requirements for ethylene oxide sterilizers (EO sterilizers) for:

- the performance and design of sterilizers intended to deliver a process capable of sterilizing medical devices;
- the equipment and controls of these sterilizers, needed for operation, control and monitoring of the sterilization processes;
- the test equipment and test procedures used to verify the sterilizer performance specified by this document.

1.3 This document does not cover sterilizers which employ the injection of EO or mixtures containing EO directly into packages or into a flexible chamber.

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*

EN 868-4:2017, *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 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 60073:2002, *Basic and safety principles for man-machine interface, marking and identification - Coding principles for indicators and actuators (IEC 60073:2002)*

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 61511-1:2017,¹ *Functional safety - Safety instrumented systems for the process industry sector - Part 1: Framework, definitions, system, hardware and application programming Requirements (IEC 61511-1:2016 + COR1:2016)*

EN 62366-1:2015,² *Medical devices Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015)*

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 3166-1:2020, *Codes for the representation of names of countries and their subdivisions - Part 1: Country code (ISO 3166-1:2020)*

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 10993-7:2008,³ *Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)*

EN ISO 11135:2014,⁴ *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation, and routine control of a sterilization process for medical devices (ISO 11135:2014)*

EN ISO 11138-1:2017, *Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)*

EN ISO 11138-2:2017, *Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)*

EN ISO 11607-1:2020,⁵ *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)*

EN ISO 12100:2010, *Safety of machinery - General principles for design- Risk assessment and risk reduction (ISO 12100:2010)*

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

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)*

ISO 639:2023, *Code for individual languages and language groups*

ISO 8000-1:2022, *Data quality - Part 1: Overview*

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

ISO 8601-1:2019,⁷ *Date and time - Representations for information interchange - Part 1: Basic rules*

¹ As impacted by EN 61511-1:2017/A1:2017.

² As impacted by EN 62366-1:2015/AC:2015/A1:2020.

³ As impacted by EN ISO 10993-7:2008/AC:2009/A1:2022.

⁴ As impacted by EN ISO 11135:2014/A1:2019.

⁵ As impacted by EN ISO 11607-1:2020/A1:2023.

⁶ As impacted by EN ISO 14971:2019/A1:2021.

⁷ As impacted by ISO 8601-1:2019/AMD 1:2022.

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:

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

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.

Note 2 to entry: There is likely to be more than one access device all of which can be different depending on function.

[SOURCE: EN ISO 11139:2018/A1:2024, 3.4, modified — Notes 1 and 2 to entry added.]

3.2

aeration

part of the sterilization process during which either the sterilizing agent or its reaction products, or both, desorb from the health care product until predetermined levels are reached

Note 1 to entry: This can be performed within the sterilization chamber or in a separate chamber or room.

[SOURCE: EN ISO 11135: 2014, 3.7, modified — Note 1 to entry added and changed “sterilization cycle” to “sterilization 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/A1:2024, 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/A1:2024, 3.29]

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/A1:2024, 3.31]

3.6**chamber**

part of equipment in which a load is processed

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

3.7**conditioning**

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

[SOURCE: EN ISO 11139:2018/A1:2024, 3.58, modified — “product” is changed to “load”.]

3.8**control**

regulation of variables within specified limits

[SOURCE: EN ISO 11139:2018/A1:2024, 3.63]

3.9**cycle complete**

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

Note 1 to entry: Upon indication of “cycle complete” in the sterilizer, the processed load can need a period of aeration using a separate operating cycle or in a separate chamber.

[SOURCE: EN ISO 11139:2018/A1:2024, 3.71, modified — Note 1 to entry has been added.]

3.10**cycle parameter**

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

Note 1 to entry: See also 3.24, process parameter.

[SOURCE: EN ISO 11139:2018/A1:2024, 3.72, modified — Note 1 to entry added.]

3.11**cycle variable**

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

Note 1 to entry: Process variables that are used by the automatic controller to control, monitor, indicate or record are also cycle variables, so a cycle variable can also be a process variable, e.g. time.

Note 2 to entry: Pressure can be a cycle variable.

Note 3 to entry: See also 3.26, process variable.

[SOURCE: EN ISO 11139:2018/A1:2024, 3.74, modified — Note 1, 2 and 3 to entry has been added.]

3.12**double-ended**

having separate doors for loading and unloading in separate areas

[SOURCE: EN ISO 11139:2018/A1:2024, 3.92, modified — Note 1 to entry deleted.]

3.13

exposure stage

cycle stage between the introduction of the sterilizing 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.

[SOURCE: EN ISO 11139:2018/A1:2024, 3.111]

3.14

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/A1:2024, 3.116]

3.15

flushing

purging
removing by displacement with a fluid

[SOURCE: EN ISO 11139:2018/A1:2024, 3.121]

3.16

indicate

display a value, condition, or stage of process

[SOURCE: EN ISO 11139:2018/A1:2024, 3.139]

3.17

load

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

[SOURCE: EN ISO 11139:2018/A1:2024, 3.155]

3.18

maximum allowable working pressure

MAWP

maximum pressure to which a component is designed to be subjected to and which is the basis for determining the strength of the component under consideration

Note 1 to entry: The maximum pressure which can be applied to a specified product without compromising safety, quality or performance can be given in the process specification.

3.19

measuring chain

series of elements of a measuring instrument 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/A1:2024, 3.165]

3.20**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 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]

3.21**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/A1:2024, 3.180]

3.22**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/A1:2024, 3.188]

3.23

process challenge device

PCD

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

[SOURCE: EN ISO 11139:2018/A1:2024, 3.205]

3.24

process parameter

specified value for a process variable

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

Note 2 to entry: See also 3.10, cycle parameter.

[SOURCE: EN ISO 11139:2018/A1:2024, 3.211, modified — Note 2 to entry added.]

3.25

process temperature

specified chamber temperature for the sterilization cycle

3.26

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/A1:2024, 3.213]

3.27

product

tangible result of a process

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

[SOURCE: EN ISO 11139:2018/A1:2024, 3.217]

3.28

record, verb

<data> collect, store, and make accessible

[SOURCE: EN ISO 11139:2018/A1:2024, 3.223]

3.29

recorder

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

[SOURCE: EN ISO 11139:2018/A1:2024, 3.224]

3.30**Response time** **τ_{90}**

<sensor> period required for a 90 % change in sensor output when exposed to a step change in the variable being measured

[SOURCE: EN ISO 11139:2018/A1:2024, 3.234]

3.31**risk assessment**

overall process comprising a risk analysis and a risk evaluation

[SOURCE: EN ISO 14971:2019, 3.20]

3.32**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]

3.33**services**

supplies from an external source needed for the function of equipment

EXAMPLE Electricity, water, compressed air, drainage.

[SOURCE: EN ISO 11139:2018/A1:2024, 3.252, modified – EXAMPLE has been added.]

3.34**sterilant**

chemical or combination of chemicals used to generate a sterilizing agent

[SOURCE: EN ISO 11139:2018/A1:2024, 3.268]

3.35**sterile**

free from viable microorganisms

[SOURCE: EN ISO 11139:2018/A1:2024, 3.271]

3.36**sterilization cycle**

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

[SOURCE: EN ISO 11139:2018/A1:2024, 3.279, modified — Note 1 to entry added.]

3.37**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 load (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/A1:2024, 3.284, modified — The word “product” in Note 1 to entry is changed to “load”.]

3.38

sterilizer

equipment designed to achieve sterilization

[SOURCE: EN ISO 11139:2018/A1:2024, 3.287]

3.39

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/A1:2024, 3.288]

3.40

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/A1:2024, 3.306]

3.41

usable chamber space

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

[SOURCE: EN ISO 11139:2018/A1:2024, 3.311]

3.42

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/A1:2024, 3.314]

3.43

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/A1:2024, 3.325]

4 General

4.1 Product definition

4.1.1 The type of sterilizer shall be specified and designated in the technical documentation. Each sterilizer type shall be type tested.

4.1.2 If alterations are made to the sterilizer a design review and risk assessment shall be carried out to assess if a new type has been created and therefore additional type tests required. Records of the design review and risk assessment shall be maintained in the technical documentation.

Conformance is demonstrated by inspection of the technical documentation.

4.1.3 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 and sterilant 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) a mirror image of the original orientation does not constitute a new type;
- d) the same control system with all fixed sensors located in the same position and orientation;
- e) the same pre-set programmes of operating cycle(s) including the same cycle parameters.

NOTE 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.

4.1.4 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) amendment of the delivered process (and associated stages) whereby there is no variation to the sterilizer equipment design, 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.

4.2 Equipment development

4.2.1 The design and development processes for a sterilizer shall be established, implemented and maintained within a formal quality system. 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 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.

4.2.2 If a new sterilization process is developed for implementation into a sterilizer, a risk analysis shall be performed and documented to ensure that any additional risk is considered for the design and that the new process does not constitute a new type (see 4.1.4).

NOTE 1 EN ISO 14971:2019 provides information for a risk management system for medical devices.

NOTE 2 EN ISO 12100:2010 provides information for risk management of machinery.

Conformance is demonstrated by inspection of the technical documentation.

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.

Conformance is demonstrated by inspection.

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 5.1.3.1. The general principles for design, risk assessment and risk reduction specified in either EN ISO 14971:2019 or EN ISO 12100:2010 shall be used. Technical solutions shall consider applicable standards including EN IEC 61010-2-040:2021 and EN 61511-1:2017.

Conformance is demonstrated in accordance with EN IEC 61010-2-040:2021 as detailed in 5.1.2.

5.1.1.2 Sterilizers shall incorporate means of protection from unauthorized access that could 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 80001-1:2021, EN ISO/IEC 27001:2023, EN ISO/IEC 27002:2022, UL 2900-1:2017 and ISO/IEC 21823-1:2019.

Conformance is demonstrated by inspection of the technical documentation.

5.1.2 Protective measures

5.1.2.1 General

Protective measures for the design of the sterilizer should consider the state of the art and applicable standards according to 5.1.2.2.

NOTE Depending on the type of sterilizer (see 4.1) and its application, the application range (e.g. health care, industrial) 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 (see 10.1).

5.1.2.2 Specific requirements

The following protective systems and measures shall apply:

With regard to 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 and documentation, sterilizers shall comply with EN IEC 61010-2-040:2021, 5.1 and 5.2. See also 11.4.
- b) For the protection against electric shock, sterilizers shall comply with EN IEC 61010-2-040:2021, Clauses 4 and 6.
- c) For the protection against mechanical hazards and hazards related to mechanical functions, sterilizers shall comply with EN IEC 61010-2-040:2021, Clauses 4 and 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, Clauses 4 and 7.
- 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 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, sterilizers 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.

- k) For the protection by interlocks, sterilizers shall comply with EN IEC 61010-2-40:2021, Clause 15 (see also 5.2.3). For the protection against radiation, including laser sources, sterilizers shall comply with EN IEC 61010-2-040:2021, Clauses 12.1, 12.3 and 12.6.

Conformance of the sterilizer with the stated requirements is demonstrated by application of related test procedures provided by the references (see also Annex G).

5.1.2.3 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, force and temperature specified in EN IEC 61010-2-040:2021, 7.3.4 and 10.1 are exceeded.

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

Conformance is demonstrated by visual inspection and inspection of the technical documentation.

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

The immunity performance criteria selected shall ensure that sterilizer performance is met when exposed to disturbance phenomena of EN IEC 61326-1:2021, 10.1.

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

Conformance is demonstrated in accordance with EN IEC 61326-1:2021, Table 1, Table 2 or Table 3, as applicable.

5.1.2.5 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 1 The EN 13445 series and EN 764-7:2002 and EN ISO 20417:2021 are deemed to address essential requirements of the Directive 2014/68/EU on pressure equipment [18], see also 5.3.

NOTE 2 Additional guidance is given in EN ISO 12100:2010.

Conformance is demonstrated by inspection of the technical documentation.

5.1.2.6 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 might 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.

NOTE A suitable symbol is specified in EN IEC 61010-2-040:2021, 10.1.

Conformance is demonstrated by visual inspection and inspection of the technical documentation.

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, Clauses 4, 5, 6 and 7. Specific requirements and results shall be established and documented.

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

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

NOTE EN ISO 12100:2010 or EN 61508-1:2010 can provide further information.

Conformance is demonstrated by inspection of the technical documentation, see also 11.3 and 11.4.

5.1.3.3 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 documentation of the usability verification/ validation in accordance with EN 62366-1:2015.

5.2 Sterilizer chamber

5.2.1 Dimensions

5.2.1.1 The internal dimensions of the chamber shall be specified by reference to the principal dimensions at specified positions, measured in millimetres expressed as 000 x 000 or 000 x 000 x 000:

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

Conformance is demonstrated by inspection of the technical documentation.

5.2.1.2 The usable chamber space shall be specified. The following dimensions shall be specified in millimetres expressed as 000 x 000 or 000 x 000 x 000:

- a) for cylindrical horizontal or cylindrical vertical usable chamber space:

- 1) the first three digits the diameter of the usable chamber space;
 - 2) the last three digits the depth of the usable chamber space;
- b) for rectangular parallelepiped usable chamber space:
- 1) the first three digits the width of the usable chamber space;
 - 2) the next three digits the height of the usable chamber space;
 - 3) the final three digits the depth of the usable chamber space;
- c) for other configurations, the chamber shall be specified in analogy to a) or b);
- d) if any dimension exceeds 999, then four digits shall be used without a decimal point.

Conformance is demonstrated by inspection of the technical documentation.

5.2.2 Doors and interlocks of the sterilizer chamber

5.2.2.1 The chamber shall be provided with one or two doors.

Conformance is demonstrated by inspection of the technical documentation.

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

Conformance is demonstrated by application testing.

5.2.2.3 It shall not be possible to open a sterilizer door during an operating cycle.

Conformance is demonstrated by inspection of the technical documentation.

5.2.2.4 In case of an interrupted cycle (e. g. due to a fault), opening of the door shall require the use of an access device and conditions in the chamber that will not create a hazard (e.g., presence of EO).

Conformance is demonstrated by inspection of the technical documentation.

5.2.2.5 The sterilizer design shall allow maintenance of the door seals in accordance with the user instructions without the need to dismantle the door assembly.

Conformance is demonstrated by inspection of the technical documentation.

5.2.2.6 Once a sterilization cycle is initiated it shall not be possible to open the unloading door until a “cycle complete” indication is obtained.

Conformance is demonstrated by inspection of the technical documentation.

5.2.2.7 For operating cycles dedicated for test or user equipment maintenance purposes only, the indication of the cycle being completed shall be different from the cycle complete indication of a sterilization cycle.

Conformance is demonstrated by inspection of the technical documentation.

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

Conformance is demonstrated by inspection of the technical documentation.

5.2.2.9 Except for equipment maintenance purposes, it shall not be possible on double-ended sterilizers to open both sterilizer doors at the same time.

Conformance is demonstrated by application testing.

5.2.2.10 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.

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

Conformance is demonstrated by application testing.

5.2.2.12 For double-ended sterilizers, 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.

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

5.2.2.13 For double-ended sterilizers in routine operation for sterilization it shall not be possible to open the unloading door until a "cycle complete" indication is obtained.

Conformance is demonstrated by application testing.

5.2.2.14 For test purposes, a key, code, or tool may be required to open either the loading or the unloading door.

Conformance is demonstrated by inspection of the technical documentation.

5.2.2.15 For dedicated test or equipment maintenance cycles, the records shall clearly indicate that this is not a routine sterilization cycle. The 'cycle complete' indication on the sterilizer shall be different from the normal cycle complete indication and/or opening the unloading door may require the use of a special key, code or tool as specified by the manufacturer.

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

5.2.2.16 If operating the doors can be controlled from a control room, an indication of which door can be opened shall also be provided in the control room.

Conformance is demonstrated by visual inspection and application testing.

5.2.2.17 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 a door is unlocked or unsealed.

Conformance is demonstrated by inspection of the technical documentation.

5.2.3 Chamber integrity

If a leak into or from 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 a leak test(s) capable of detecting that leak, see 6.8.2.

Conformance is demonstrated by inspection of the technical documentation.

5.2.4 Pressure vessels

5.2.4.1 If a pressure vessel according to the Pressure Equipment Directive (PED) is used for the sterilizer, the vessel shall comply with EN 13445-2:2002+A1:2023, EN 13445-5:2021+A1:2024 and EN 764-7:2002. Other pressure vessel standards may apply if equivalence with respect to safety is verified.

Conformance is demonstrated by the technical documentation.

5.2.4.2 If a stainless-steel steam boiler as a part of the sterilizer is used, it shall comply with EN 14222:2021.

Conformance is demonstrated by the technical documentation.

5.2.5 Uniformity of conditions, temperature control and insulating the sterilizer chamber

5.2.5.1 Chamber inner surfaces shall be temperature controlled within a specified range during sterilization cycles.

Conformance shall be determined using the test methods described in Annex C.

5.2.5.2 The sterilizer chamber heating system shall be provided with an over-temperature cut-out which interrupts the chamber heating to prevent over-heating of the chamber. The temperature at which the cut-out activates shall be specified. The over-temperature cut-out shall be independent of the temperature control function of the automatic controller. A fault shall be indicated if the over-temperature cut out is activated.

Conformance is demonstrated by inspection of the technical documentation.

5.2.5.3 Where hot outer surfaces of the sterilizer chamber can cause a burn hazard and to reduce heat transmission to the environment, these surfaces shall be insulated, except where this will interfere with the intended function of the sterilizer. This also applies to the vaporization system.

Conformance is demonstrated by inspection.

5.3 Further functional components

5.3.1 Pipework and fittings

5.3.1.1 Components, pipework and fittings, including ancillary vessels, connected to the sterilizer chamber shall be rated at or above the maximum allowable working pressure of the sterilizer chamber. Relevant standards shall be taken into account (see 5.2.4) when specifying the use of such equipment.

NOTE The pressured equipment directive can be applicable.

Conformance is demonstrated by the technical documentation.

5.3.1.2 All components in the piping network shall be marked and/or identified according to their functions and according to EN 60073:2002.

Conformance is demonstrated by visual inspection.

5.3.1.3 The maintenance or replacement frequency for all components of the equipment shall be established and documented.

NOTE Pressure relief systems can prevent hazardous situations.

Conformance is demonstrated by inspection of the technical documentation.

5.3.1.4 Pipework shall be designed to prevent accumulation of condensate.

NOTE Insulation of pipework can reduce the amount of condensate formed.

Conformance is demonstrated by inspection.

5.3.1.5 All pipework and fittings carrying EO shall be made by welding or brazing unless the joint is intended to be demountable for equipment maintenance purposes and shall be pressure tested prior to use.

NOTE Flexible hoses which are designed to, or can inadvertently, carry EO are preferably constructed from stainless steel or stainless steel internally lined with polytetrafluoroethylene (PTFE), nitrile rubber, or other material of demonstrated equivalent performance.

Conformance is demonstrated by visual inspection and inspection of the technical documentation.

5.3.1.6 Pipework and fittings, including seals, which can come into contact with process chemicals shall be made 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 hazard.

Conformance is demonstrated by inspection of the technical documentation.

5.3.2 Vaporizers

5.3.2.1 If an EO 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 according to EN IEC 61010-2-040:2021, 11.101 and 13.1.

Conformance is demonstrated by visual inspection and by inspection of the technical documentation.

5.3.2.2 Means shall be provided to prevent any excessive temperature and pressure which can create hazards, e.g. fire or explosion.

Conformance is demonstrated by inspection of the technical documentation.

5.3.2.3 EO vaporizers shall be constructed so that the heating surface in contact with EO is cleanable by the method specified by the manufacturer. The vaporizer design shall permit cleaning with minimum disassembly.

Conformance is demonstrated by inspection of the technical documentation.

5.3.3 Evacuation system

5.3.3.1 Sterilizers shall be provided with a vacuum system to remove air, EO gas, inert gas and steam or water, as applicable.

Conformance is demonstrated by inspection of the technical documentation.

5.3.3.2 The lowest absolute pressure needed to comply with the requirements for operating cycle control (see 6.8, 10.2 and 10.3) and testing (Annex B) shall be specified.

NOTE The vacuum system can be an integrated component of the sterilizer, or an external system.

Conformance is demonstrated by inspection of the technical documentation and results of application tests related to Annex B.

5.3.3.3 When a service media is used in vacuum systems (such as water in liquid ring vacuum pumps), the service media shall not be disposed of until cleared of EO below admissible levels (see also Annex E).

Conformance is demonstrated by inspection of the technical documentation.

5.3.3.4 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 10.2.

Conformance is demonstrated by inspection of the technical documentation.

5.3.3.5 Circulation systems

If gas mixtures or inert gasses are used, then forced circulation can be required to achieve homogeneous concentrations. In this case, chamber content forced circulation systems shall be monitored by the automatic controller. A recording of their satisfactory operation shall be obtained. Failure to attain satisfactory operation shall cause a fault indication.

Conformance is demonstrated by inspection of the technical documentation.

5.3.4 Framework and panelling

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

NOTE Side panelling is not required for some types of large industrial sterilizers and sterilizers designed to be recessed into existing walls providing continuous joints with the sterilizer front panelling.

Conformance is demonstrated by inspection of the technical documentation.

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

Conformance is demonstrated by inspection of the technical documentation.

5.3.4.3 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.

Conformance is demonstrated by inspection of the technical documentation.

5.3.4.3.1 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.

Conformance is demonstrated by visual inspection and inspection of the technical documentation.

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

Conformance is demonstrated by visual inspection and inspection of the technical documentation.

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

NOTE More information on access is given in EN IEC 61010-2-040:2021, 7.3.2 and 7.3.5.

Conformance is demonstrated by visual inspection and inspection of the technical documentation.

5.3.4.4 The technical documentation shall specify the maximum deviation from a horizontal plane on which the sterilizer is designed to be installed and operated.

Conformance is demonstrated by visual inspection and inspection of the technical documentation.

5.3.4.5 The technical documentation shall include the maximum floor loading the sterilizer will exert when installed.

Conformance is demonstrated by visual inspection and inspection of the technical documentation.

5.3.4.6 The technical documentation shall specify any features of the supporting floor which are necessary for the efficient and safe operation of the sterilizer, e.g. the floor coating should be impervious to water or be designed to allow collection and drainage of water spillage from the sterilizer.

Conformance is demonstrated by visual inspection and inspection of the technical documentation.

5.3.5 Loading Equipment

5.3.5.1 Loading equipment, if required according to usability assessment, shall be available separate to the sterilizer.

Conformance is demonstrated by inspection of the technical documentation.

5.3.5.2 Specified dedicated accessories intended to be used with or connected to the sterilizer shall not cause any hazard or detrimental effect on the performance of the sterilizer.

Conformance is demonstrated by inspection of the technical documentation.

5.3.5.3 The mutual compatibility of the ancillary equipment with the sterilizer shall be verified.

Conformance is demonstrated by inspection and examination of the technical documentation.

5.4 Materials

5.4.1 Chamber materials

5.4.1.1 For general requirements on materials used for pressure equipment see 5.4.

5.4.1.2 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. They shall not release any substances known to be toxic in such quantities that can create a health or environmental hazard.

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

Conformance is demonstrated by inspection of the technical documentation.

5.4.1.3 Materials internal to the chamber including permanent or temporary fixtures and fittings shall be selected to avoid corrosion and galvanic attack.

Conformance is demonstrated by visual inspection and inspection of the technical documentation.

5.4.2 Other materials used in the construction of the sterilizer

5.4.2.1 Materials used for functional parts of the sterilizer in contact with the process fluids (for example, chamber, doors, door seals, gaskets welds, ancillary items, pipe work, valves, and sensors) shall

all be made of materials which, in normal use, are thermostable and will not react with ethylene oxide, its diluent gasses or other process chemicals (for example water, compressed air and steam) in a manner and to an extent that could lead to deterioration that could:

- a) affect the operation of the sterilization cycle, e.g. by polymerization or decomposition of EO;
- b) have a detrimental effect on the materials (e.g. corrosion);
- c) release a substance known to be toxic in such quantities that would create a health or environmental hazard; or
- d) create a hazardous situation, e.g. unacceptable diffusion of EO.

Conformance is demonstrated by inspection of the technical documentation.

5.4.2.2 Due attention shall be paid to the effects of mechanical effects and differential expansion when dissimilar metals are used in contact.

NOTE 1 When selecting materials for construction, the material safety data sheet for EO can be referenced.

NOTE 2 The compatibility of materials with ethylene oxide has been addressed in literature (e.g. [33]).

Conformance is demonstrated by inspection of the technical documentation.

5.4.2.3 The admissible pressure and temperature range (see 11.2) shall be specified when selecting materials of construction.

Conformance is demonstrated by inspection of the technical documentation.

5.5 Test connections

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

5.5.2 The number and types of test connections and how test equipment can be introduced into the sterilizer chamber shall be specified.

5.5.3 Test connection(s) shall be designed in such a way that all areas of the chamber can be reached in a suitable manner with suitable measurement techniques.

NOTE 1 Keeping the number of test connections to a minimum reduces the risk of leakage. One test connection can be used for multiple measurements by use of adaptors.

NOTE 2 Failure to provide test connections can complicate the performance of validation.

Conformance is demonstrated by inspection of the technical documentation.

5.5.4 Test connections shall be at points of easy access, but not restricting media transport in pipes (e.g. steam, sterilizing agent, air).

Conformance is demonstrated by inspection of the technical documentation.

5.5.5 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.

5.5.6 The test connections shall be sealed and provided with means to prevent physical or chemical damage.

Conformance is demonstrated by inspection of the technical documentation.

5.5.7 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 could 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.

5.5.8 Following the use of test connections, a leak test should be performed to confirm the seal integrity of the sterilizer.

Conformance is demonstrated by inspection of the technical documentation.

5.6 Vibration

5.6.1 Vibrations from sterilizers shall be reduced by design and selection of components that limit vibrations, particularly at the source.

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

NOTE 1 Vibration from other sources applicable to the intended use of the sterilizer can also be considered.

NOTE 2 Guidance to reduce vibration at the 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 of the technical documentation.

5.7 User interfaces

5.7.1 User interface located in remote operating facility

5.7.1.1 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.

5.7.1.2 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.

5.7.1.3 If a remote operating facility is used, a risk analysis shall be performed to ensure safe operation and service of the sterilizer and the safety of the installation area.

Conformance for 5.7.1 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 using an access device (see 6.4.2).

5.7.3 Sterilizers shall be provided with the indicating devices specified in 6.6.

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. This shall require the use of an access device. The activation of any service mode shall be by use of an access device and shall be clearly indicated in order to avoid safety features being inactivated during normal operations.

Conformance is demonstrated by inspection.

NOTE Additional information regarding intervention safety and environmental aspects are 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).

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. Instruments and gauges shall be readable by normal or corrected vision from a distance of 1 m and with a minimum external illumination of 200 lx.

Conformance is demonstrated by inspection.

5.7.7 If an instrument on the sterilizer is adjustable for maintenance purposes, adjustment shall require the use of an access device.

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.

5.8 Transport

5.8.1 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 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.

NOTE EN 61010-1:2010, 7.5 provides information for lifting and carrying the equipment.

Conformance is demonstrated by inspection of the technical documentation.

5.8.2 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, and no moving parts can cause a hazard.

Conformance is demonstrated by inspection.

5.8.3 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.

Conformance is demonstrated by inspection of the technical documentation.

6 Indicating, monitoring, controlling and recording devices

6.1 General

6.1.1 General

The sterilizer comprises an automatic controller with pre-set programmes and cycle(s) (see 6.2). The controller is part of a control and monitoring system (see 6.3) that allows detection of failure (see 6.4) and comprises instrumentation, indicating devices and recorder sub-units (see 6.5, 6.6 and 6.7).

6.1.2 Pre-set programme

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

NOTE 1 They are intended to ensure that all chemical/physical conditions necessary for the efficacy of the operating cycles can be achieved throughout the specific cycle stages.

NOTE 2 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 and by successful type tests according to Annexes A, B, C and D.

6.1.3 Automatic controller

6.1.3.1 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.

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

NOTE See EN 60204-1:2018 or EN IEC 60335-1:2023. Verification can be achieved by assessing conformance with EN 60204-1:2018 or EN IEC 60335-1:2023. EN 60204-1:2018 applies to non-portable electrical, electronic, and programmable electronic equipment and systems to machines. EN IEC 60335-1:2023 deals with the safety of electrical appliances for household and similar purposes, including appliances not intended for normal household use but which nevertheless may 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 Automatic control

6.2.1 The sterilizer shall be operated by an automatic controller with permanently stored pre-set programmes and one or more operating cycle.

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.

6.2.2 Means shall be provided to ensure that a failure in a control function does not lead to a failure in recording and interpretation of process and cycle variables such that an ineffective process appears effective. This may be achieved either by the use of independent systems for control and recording, or by a cross-check between control and recording that identifies 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 illustrated in Annex F.

Conformance is demonstrated by inspection of the technical documentation.

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.

The automatic controller shall be designed in accordance with requirements of EN 61511-1:2017 for safety critical activities identified in risk assessment.

Conformance is demonstrated by inspection of the technical documentation.

6.2.4 The pre-set programs of the automatic controller shall allow reproducible control, indication, monitoring and recording of the operating cycle to ensure that the pre-set programs perform within specified tolerances as intended.

Conformance is demonstrated by inspection of the technical documentation and the results of type testing.

6.2.5 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.

6.2.6 Safety related software, including software for monitoring and control and recorders shall be verified and validated according to its classification (see e.g. EN 62304:2006). The methods used in the verification and validation processes shall be selected based on the intended purpose of the software. The methods shall be justified and specified.

NOTE Regarding software information, see e.g. EN 61508 (all parts), EN 62304:2006 and EN IEC 62061:2021.

Conformance is demonstrated by inspection of the technical documentation.

6.2.7 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 visual inspection.

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

NOTE To fail the system can be electronic or mechanical.

Conformance is demonstrated by inspection of the technical documentation.

6.2.9 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.

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

Conformance is demonstrated by inspection of the technical documentation.

6.2.11 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, ancillary equipment or the operating environment, considering EO and inert gases 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).

Conformance is demonstrated by inspection of the technical documentation.

6.2.12 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.

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

Conformance is demonstrated by inspection of the technical documentation.

6.2.14 Access to any control devices shall only be possible by use of an access device.

Conformance is demonstrated by inspection of the technical documentation.

6.2.15 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. clauses 13.1.101, 13.1.102, 13.101, 14.103 and 14.104).

Conformance is demonstrated by inspection of the technical documentation.

6.3 Control and monitoring system

6.3.1 The control and monitoring system shall comprise different subunits (for computing, measuring chains, instrumentation and safety) and directs operation of the sterilizer using software modules for data collection and processing, cycle control, including safety cycle parameter and status indications, operating controls, independent recording and data storage, process evaluation, and fault indication. See also Annex F.

Conformance is demonstrated by inspection of the technical documentation considering the principles of the concepts described in Annex F.

6.3.2 The control and monitoring system shall have separate measuring chains for the measurement of control data and independent data for the monitoring system (see also 6.5 and 6.7). Independent measurement systems with separate measurement chains for cycle control and monitoring shall be applied to defined cycle variables and process variables. Separate analogue to digital converters shall be used for the control data and monitoring independent data (see Annex F). Risk analysis identifies which cycle variables or process variables require redundant supervision.

Conformance is demonstrated by inspection of the technical documentation considering the principles of the concepts described in Annex F.

6.3.3 In order to achieve reproducible sterilization cycles, in EO sterilizers the following cycle variables and process variables shall be considered for control, monitoring, indication and recording, but are not limited to:

- a) temperature (see 6.5.2, 6.6.2.1);
- b) pressure (see 6.5.3, 6.6.2.2);

- c) time (see 6.5.4, 6.6.2.3);
- d) humidity (see 6.5.6);

NOTE 1 See also 6.5.1 and 7.2.

- e) sterilant composition and amount supplied to the process in order to control the sterilizing agent (see 6.5.5, 6.6.2.4).

NOTE 2 For example, volume, dose, mass flow, concentration, partial pressure can be used as appropriate.

Conformance is demonstrated by inspection of the technical documentation.

6.3.4 The control and monitoring system shall have segregated software modules that process the control data and the independent data independently of each other.

Conformance is demonstrated by inspection of the technical documentation.

6.3.5 The control data shall be provided to the control function from the data processing system and the control measurement chain.

Conformance is demonstrated by inspection of the technical documentation.

6.3.6 The independent data shall be provided as a one-way flow to data retention.

NOTE This does not exclude the transfer of informative data between the control function and failure detection, and data retention, via a combined system for data transfer.

Conformance is demonstrated by inspection of the technical documentation.

6.3.7 The control and monitoring system shall include means for failure detection. This shall receive both processed control data and independent data and shall indicate a failure if the control data and independent data differ from specified conditions.

Conformance is demonstrated by inspection of the technical documentation.

6.3.8 The independent data and the control data shall be stored in a data retention module, along with notification of failures. These data shall be transferred to the recording system in accordance with 6.7 (see 6.7 and Annex F.).

NOTE The external device can be a specific local device, or a remote data storage device.

6.3.9 A printer may be provided as an option and can be built into the sterilizer facia or as a separate external device.

Conformance is demonstrated by inspection of the technical documentation.

6.4 Failure

6.4.1 General

6.4.1.1 Failure of items and parameters identified by risk analysis to be critical to process or safety, including the operating equipment and services, shall be detected by the monitoring system of the equipment.

NOTE 1 A failure can lead to different types of indications depending upon its potential effects and urgency, such as audible/visual alarms, warnings, error indications, messages, displays, as well as subsequent automated responses of equipment or correction by the operator.