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

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National foreword

This British Standard is the UK implementation of EN 1422:2014. It supersedes BS EN 1422:1997+A1:2009 which is withdrawn.

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

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

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

This European Standard was approved by CEN on 17 April 2014.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN 1422:2014) has been prepared by Technical Committee CEN/TC 102 “Sterilizers for medical purposes”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2014 and conflicting national standards shall be withdrawn at the latest by May 2017.

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

This document supersedes EN 1422:1997+A1:2009.

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

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

Annexes A, B, C and D are normative and form part of this European Standard.

Annexes E and ZA are for information only.

The standard is a full technical revision of the previous version. The following amendments have been made in comparison with EN 1422:1997+A1:2009:

— new specification of the scope of the standard, e.g. explicit exclusion of sterilizers which employ the injection of EO or mixtures containing EO directly into packages or into a flexible chamber and removal of different types A and B of EO-sterilizers ;

— normative references have been updated;

— layout of the standard brought in line with the standard for LTSF-sterilization (EN 14180);

— the additional requirements from the machinery directive, introduced by the revision of the medical devices directive 2007/47/EC have been addressed (see revised Annex ZA), i.e. update of technical requirements and Tables ZA.1 and ZA.2;

— requirements have been rephrased to be performance requirements instead of design requirements;

— addition of an environmental checklist;

— Annex B has been thoroughly revised and Annex D has been deleted.

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

Introduction

Ethylene oxide (EO) sterilizers employing EO gas as the sterilant, either as a pure gas or in admixture with other gases, are primarily used for the sterilization of heat labile material or product.

The EO-sterilizer specified in this European standard can be used for medical, dental, pharmaceutical veterinary and industrial or related purposes.

The tests described in this European Standard are reference tests intended for use in demonstrating conformity with the performance requirements specified in this European Standard. They can 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 European Standard does not cover validation and routine control of EO processes (see prEN ISO 11135:2012). EO is a highly reactive chemical which can present a toxic, flammable or explosive hazard if incorrectly handled (see Annex E).

The performance requirements specified in this document are not intended for the process to be effective in inactivating the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeld-Jakob disease.

Planning and design of products complying with 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 E of this standard.

By performing tests concurrently and/or in a logical sequence, the total number of tests carried out and waste arising from such tests, is reduced. As a result the burden on the environment can be reduced (see also Annex E).

1 Scope

This European Standard 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.

This European Standard specifies requirements for ethylene oxide sterilizers (EO-sterilizers) working at super or sub-atmospheric pressure for:

— the performance and design of sterilizers to ensure that the process is capable of sterilizing medical devices;

— the equipment and controls of these sterilizers necessary for the validation and routine control of the sterilization processes.

The test loads described in this European Standard are selected to represent a number of loads for the evaluation of the performance of EO sterilizers for medical devices. However, specific loads may require the use of other test loads.

This European Standard does not specify those tests which are necessary to determine the probability of a processed product being sterile, nor the routine quality control tests required prior to release of sterile product. These topics are addressed in prEN ISO 11135:2012.

This European Standard does not specify requirements for occupational safety associated with the design and operation of EO sterilization facilities.

NOTE 1 For further information on safety, see examples in the Bibliography. National or regional regulations can exist.

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

NOTE 2 See EN ISO 14937.

This European Standard is not intended as a checklist for suitability of an existing EO sterilizer when assessing compliance with prEN ISO 11135:2012. This standard is not intended to be applied retrospectively.

This European Standard does not cover analytical methods for determining levels of residual EO and/or its reaction products.

NOTE 3 For further information see ISO 10993-7.

2 Normative references

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

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

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

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

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

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

EN 14222, *Stainless steel shell boilers*

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

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

EN 61326-1:2006, *Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 1: General requirements (IEC 61326-1:2005)*

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

prEN ISO 11135:2012, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO/DIS 11135:2012)*

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

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

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

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

3 Terms and definitions

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

3.1
aeration
part of the sterilization process during which ethylene oxide and/or its reaction products desorb from the medical device until predetermined levels are reached

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

[SOURCE: prEN ISO 11135:2012, 3.1]

3.2
air admission stage
stage of the cycle beginning with the attainment of the pre-set pressure on the last evacuation of the flushing stage or sterilant removal stage when filtered air is admitted to allow the chamber pressure to equilibrate with ambient pressure

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

3.3
automatic controller
programmed device that, in response to cycle parameters, operates the sterilizer sequentially through the operating cycle(s)

3.4
biological indicator
test system containing viable microorganisms providing a defined resistance to a specified sterilization process

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

3.5
calibration
set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards

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

3.6
conditioning
treatment of product within the sterilization cycle, but prior to ethylene oxide admission, to attain a predetermined temperature and relative humidity

Note 1 to entry: This part of the sterilization cycle can be carried out either at or above atmospheric pressure or under vacuum.

3.7
controlling
regulating variables to specification

3.8
cycle complete
indication that the operating cycle has been completed according to programme and that the sterilized load is ready for removal from the sterilizer chamber

Note 1 to entry: Upon indication of “cycle complete” a further period of aeration of the processed load can be required.

3.9
ethylene oxide exposure time
the period of the sterilization cycle between the end of EO injection and the beginning of EO removal

3.10
fault
one or more of the process parameters lying outside of its/their specified tolerance(s)

[SOURCE: ISO/TS 11139:2006, 2.19]

3.11
flushing
stage of the sterilization cycle in which the ethylene oxide is removed from the load and free chamber space of the sterilization chamber

Note 1 to entry: Flushing is also known as purging.

3.12
indicating
displaying a value, fault or cycle stage

3.13
medical device
any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

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

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

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

— supporting or sustaining life,

— control of conception

— disinfection of medical devices,

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

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

[SOURCE: EN ISO 13485:2012, 3.7]

3.14
monitoring
checking against specifications

3.15
preconditioning
treatment of product, prior to the sterilization cycle, in a room or chamber to attain specified limits for temperature and relative humidity

[SOURCE: prEN ISO 11135:2012, 3.25]

3.16
process challenge device
PCD
item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process

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

Note 1 to entry: The device is so constituted that a physical, biological or chemical indicator can be put in the place which is the most difficult to reach by sterilizing agent(s). Interference of the indicator with the function of the process challenge device is not acceptable.

3.17
process parameter
specified value for a process variable

[SOURCE: ISO/TS 11139:2006, 2.34]

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

3.18
process temperature
specified chamber temperature for the sterilization cycle

3.19
process variable
condition within a sterilization process, changes in which alter microbicidal effectiveness

[SOURCE: ISO/TS 11139:2006, 2.35]

EXAMPLES Time, temperature, pressure, concentration, humidity.

3.20
recording
collecting and storing data

Note 1 to entry: Data storing can be realised electronically or by hard copy.

3.21
response time
time required for a 90 % change in sensor output when exposed to a step change in the variable being measured

3.22
risk assessment
overall process comprising a risk analysis and a risk evaluation

[SOURCE: EN ISO 14971:2012, 2.18]

3.23
risk control
process through which decisions are reached and protective measures are implemented for reducing risks to, or maintaining risks within, specified levels

[SOURCE: EN ISO 14971:2012, 2.19]

3.24
services
supplies from an external source, needed for the function of equipment

EXAMPLE Electricity, water, compressed air, drainage.

[SOURCE: ISO/TS 11139:2006, 2.41]

3.25
sterile
free from viable microorganisms

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

3.26
sterilizer
apparatus designed to achieve sterilization

[SOURCE: EN 285:2006+A2:2009, 3.35]

3.27
EO sterilization cycle
treatment in a sealed chamber comprising air removal, conditioning (if used), injection of ethylene oxide, exposure to ethylene oxide, removal of ethylene oxide and flushing (if used), and air/inert gas admission

[SOURCE: prEN ISO 11135:2012, 3.48]

Note 1 to entry: EO sterilization cycle does not include aeration (if required).

3.28
sterilization load
product(s) to be, or that has been, sterilized together using a given sterilization process

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

3.29
software validation
confirmation and provision of objective evidence that the requirements for a specific intended use or specification of the software have been fulfilled

Note 1 to entry: In accordance to EN ISO 9000.

3.30
sterilization process
series of actions or operations needed to achieve the specified requirements for sterility

[SOURCE: ISO/TS 11139:2006, 2.49]

Note 1 to entry This series of actions or operations includes pre-treatment (if necessary), exposure to the EO under defined conditions and any necessary post-treatment required for the removal of EO and its by-products to the point where it is safe for the operator to remove the load from the sterilization chamber. It does not include any cleaning, disinfection or packaging operations that precede the sterilization process.

3.31
type test
series of checks and tests for a particular design of sterilizer to demonstrate compliance with the requirements of this European Standard

Note 1 to entry: Additional type tests can be required by the purchaser to show compliance to a specific specification.

3.32
usable chamber volume
defined space within the sterilizer chamber, which is not restricted by fixed or mobile parts and which is available to accept the sterilization load

EXAMPLE The available space on a pallet of defined dimensions.

Note 1 to entry: The maximum load volume is likely to be less than the usable chamber volume as space is required to allow for circulation of sterilant gasses.

[SOURCE: prEN ISO 11135:2012, 3.56]

3.33
verification
confirmation through provision of objective evidence that specified requirements have been fulfilled

[SOURCE: EN 62304:2006, 3.33]

3.34
works test
series of tests performed prior to delivery to demonstrate compliance of equipment with its specification

Note 1 to entry: In accordance with EN ISO 15883-1:2009.

4 Technical requirements

4.1 General

If a pressure vessel according to the Pressure Equipment Directive (PED) is used for the sterilization, the vessel shall comply with EN 13445-3, EN 13445-5 and EN 764-7.

If a shell boiler is used to generate the steam used in the sterilizer, it shall comply with EN 14222.

NOTE 1 See Council Directive concerning pressure equipment (97/23/EEC) [3].

NOTE 2 Sterilizer chambers that run sterilization cycles designed to operate completely below 1,5 bar, do not fall under the Pressure Vessel Directive (PED). Appropriate pressure relief valves can used to ensure over pressurisation does not occur.

NOTE 3 Other European directives can apply. Examples of directives that can apply include, but are not restricted to, the LVD [5], EMC [4], ATEX [2], REACH [10].

4.1.1 Risk control and usability

4.1.1.1 Risk assessment and risk control for sterilizer design and software shall be performed following the procedures and requirements given in EN ISO 14971:2012, Clauses 5, 6 and 7.

4.1.1.2 Risk analysis shall address the specific EO-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.

4.1.2 Materials

4.1.2.1 All materials used for the construction of an EO-sterilizer and instrumentation (for example, door seals, gaskets welds, ancillary items, pipe work, valves and sensors) which can come into contact with EO and other process chemicals (for example water, compressed air and steam) shall be of materials which, under the designed operating conditions:

— are not corroded by EO, its diluent gasses or potential contaminants or steam and/or be subject to metallic corrosion;

— will not react with EO, its diluent gasses or potential contaminants or steam;

— will not promote the polymerization or decomposition of EO;

— will not allow diffusion of EO to an extent which impairs their safe operation.

Due attention should 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.[6]).

4.1.2.2 The admissible pressure and temperature range (see 9.2) shall be specified when selecting materials for construction.

4.2 Sterilizer chamber

4.2.1 Chamber size

The internal dimensions of the chamber shall be designated by reference to the principle dimensions, measured in millimetres:

a) for cylindrical horizontal or cylindrical vertical chambers:

   — diameter,

   — depth;

b) for rectangular parallelepiped chambers:

   — width,

   — height,

   — depth;

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

4.2.2 Doors, closures and interlocks of the sterilizer chamber

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

NOTE For automated loading and unloading systems, loading and unloading doors can be opened simultaneously for loading and unloading during routine sterilization cycles.

4.2.2.2 Once a sterilization cycle is initiated, it shall not be possible to open the unloading door until a “cycle complete” indication is obtained, without the use of a special key, code or tool as specified by the manufacturer.

4.2.2.3 It shall not be possible to open any sterilizer door during a cycle. For maintenance purposes it shall only be possible to open any door when the sterilizer is in a condition that presents no hazard to the operator or ancillary equipment, using a special key, code or tool as specified by the manufacturer.

4.2.2.4 In case of an interrupted cycle (e.g. due to a fault), the sterilizer shall be brought to a condition that presents no hazard to the operator or ancillary equipment, taking into account EO and inert gases being used during the process. Opening of the door shall require the use of a special key, code or tool as specified by the manufacturer.

4.2.2.5 Provision shall be made to permit access to the contact surfaces for the purposes of cleaning and replacing the door seal.

4.2.2.6 For dedicated test or maintenance cycles, the records shall clearly indicate that this is not a routine sterilization cycle. The ‘cycle complete’ indication on the sterilizer may 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.

4.2.2.7 The device used to start the automatic operating cycle shall be located at the loading side of the sterilizer or in the control room.

4.2.2.8 For maintenance purposes it shall be possible to open both doors simultaneously on double-ended sterilizers using a special key, code or tool as specified by the manufacturer.

4.2.2.9 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. In addition, if there is a control room, an indication of which door can be opened shall also be provided in the control room.

If the doors are controlled from a control room, no indications at the doors whether a door can be opened, are required.

4.2.2.10 The indication ‘cycle complete’ shall be cancelled when a door is opened.

NOTE After the ‘cycle complete’ indication, additional degassing/aeration could be required to achieve safe conditions for the operators.

4.2.2.11 The door closing and locking mechanism shall be designed in such a way that the operator is not endangered, such as a safety edge or an auto reverse function.

4.2.2.12 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 61010-1:2010,10.1 and EN 61010-2-040:2005, 7.1.101, 7.101 and 7.102 are exceeded.

NOTE This can be achieved, e.g. by reversing the direction of the door movement.

4.2.3 Test connections

4.2.3.1 The number and types of test connections shall be specified. It shall be specified how test equipment can be introduced into the sterilizer chamber. Test connection(s) (if fitted) 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 If the measurement of EO-concentration or RH is required, this needs to be taken into account when specifying the dimensions for the test connections to allow easy access for the measuring systems.

NOTE 2 Increasing the number of test connections increases the risk of leakage.

NOTE 3 Failure to provide test connections could complicate the performance of validation.

4.2.3.2 Test connections shall be at points of easy access, but not in pipes for media transport (e.g. steam, EO, air), and the test connections shall be specified.

4.2.3.3 The test connections shall be provided with caps and sealed with EO proof and mechanically resistant seals.

NOTE It is recommended to keep the number of test connections to a minimum for reasons of safety.

4.3 Design and construction

4.3.1 General

Components, including ancillary vessels that are connected to sterilizer chamber and that are required to contain the admissible design pressure of the chamber or higher, may need to comply with the requirements of the PED or other relevant directives.

All components in the piping network shall be marked and/or identified according to their functions (see EN 60073).

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

4.3.2 EO vaporizers

EO vaporizers shall be constructed so that the heating surface in contact with EO is cleanable by the method specified by the manufacturer.

4.3.3 Pipework and fittings

4.3.3.1 Pipework shall be designed to prevent accumulation of condensate.

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

4.3.3.2 All pipework and fittings carrying EO shall be made by welding or brazing unless the joint is intended to be demountable for maintenance purposes.

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.

4.3.4 Evacuation system

4.3.4.1 Sterilizers shall be provided with means to evacuate the chamber to meet process specifications.

NOTE 1 Minimization of the amount of water used is a consideration when designing evacuation (see also Annex E).

NOTE 2 EO can dissolve in water and oil.

4.3.4.2 The sterilizer shall be provided with a means for leak testing which shall include the sterilizer chamber and all relevant connected pipeworks and fittings.

4.3.5 Control valves

When removal of connecting pipes is necessary for maintenance of the valves connected to the chamber, it shall be possible to leak test the connecting pipes to the valves.

4.3.6 Thermal insulation

Any surface that can attain a temperature exceeding 55 °C during normal operation shall be insulated, except where this would interfere with the function and operation of the sterilizer.

4.3.7 Electrical and mechanical safety

4.3.7.1 Safety of the design shall be based on risk assessment. Technical solutions shall consider applicable standards.

NOTE 1 For general design see EN 61010–1 and EN 61010–2–040.

NOTE 2 Additional guidance is given in EN ISO 12100.

NOTE 3 For guidance regarding specific design aspects, EN 60204–1 can apply. The guidance in EN 60204–1 can reduce testing.

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

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

The immunity performance criteria selected shall ensure that sterilizer performance as specified in 5.2 is met when exposed to disturbance phenomena of EN 61326-1:2006, Table 2.

4.3.8 Air or inert gas filter

4.3.8.1 Microbial (re)contamination of the sterilization load shall be prevented.

4.3.8.2 When filters are fitted to prevent (re)contamination, they shall be readily accessible for replacement. The filter shall retain not less than 99,5 % of particles greater than 0,3 µm.

Air filters should be constructed from materials resistant to corrosion and biodegradation.

NOTE 1 A readily detachable pre-filter designed to retain dust particles greater than 25 µm is recommended to prolong the life of the filter.

NOTE 2 It is recommended that the filter material is supported in a manner which restricts its distortion and movement during use in order to minimise damage to the filter medium.

4.3.8.3 Each filter shall have a control valve fitted directly between the filter and chamber, to isolate the filter.

4.3.9 Emission control

All exhaust emissions from sterilizers shall be controlled and – if necessary – discharged via a suitable emission control system according to manufacturer's instructions.

NOTE National and local requirements for occupational health and safety and the environment can be consulted as they can apply to potential EO exposure.

4.3.10 Framework and panelling

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

NOTE Some types of large industrial sterilizers and sterilizers designed to be recessed into existing walls providing a continuous joint with the sterilizer front panelling, do not need to be provided with side panelling.

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

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.

4.3.10.3 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 1500 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 should be positioned so that it will not compromise the safety of either the product or persons.

NOTE Requirements for access are specified in EN 61010–2-040:2005, 7.3.2 and 7.3.5.

4.3.11 Loading equipment

If required for ergonomic reasons, loading equipment shall be available as a separate accessory to the sterilizer.

4.3.12 Transport

Where the weight, size or shape of the sterilizer or its various component parts prevent 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.

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

4.4 Indicating, measuring, and recording instruments

4.4.1 General

4.4.1.1 Indicating and measuring and recording instruments shall be identified as to their function. They shall be readily accessible, clearly and durably marked with their function and designed to be easy to operate and read.

4.4.1.2 The instruments shall be positioned and/or protected such that their performance is within the specified tolerances during the operation of the sterilizer.

4.4.1.3 If an indicating instrument is connected in turn to more than one sensing point, there shall be a continuous indication of the active sensor that is being monitored.

4.4.1.4 Indicating and operating instruments shall be readable when viewed at a distance of (250 ± 25) mm with normal or corrected vision in an illumination of (215 ± 15) lx.

4.4.1.5 Indicating, measuring and recording instruments shall have means to adjust *in situ* by the use of a key, code or tool without dismantling the instrument.

NOTE Where digital pressure indicators are used, an additional mechanical pressure gauge can be fitted for safety reasons. Where an analogue instrument is provided only for this purpose, the requirement for adjustment *in situ* is waived.

4.4.1.6 Additional functions fitted at recording or indicating instruments shall not jeopardise the accuracy.

4.4.1.7 When used for process control, indicating or recording purposes, means shall be provided to indicate a sensor failure.

4.4.2 Temperature sensor

4.4.2.1 When used for process control, indicating or recording purposes, temperature sensors shall have maximum permissible errors of 1 °C or less over the scale range 20 °C to 10 °C above the highest process temperature. The data sampling rate shall be high enough to ensure valid representation of the sterilization process and the response time of the sensor shall be 1 s or less.

NOTE The required sampling rate will be dependent upon the rate of change of temperature within the process. In large industrial sized chambers, the sampling rate can be once a minute. In smaller chambers, this rate will need to be increased.

4.4.2.2 A minimum of two probes to measure chamber temperature shall be used. Large volume chambers can be fitted with more than two probes so as to ensure that the system captures data that reflects the temperature throughout the chamber during use. Temperature probes should be located in the area specified as the reference measurement point and shall be easily removable for calibration purposes if necessary.

NOTE The purpose of two separate probes is to prevent the failure of one sensor from causing an out-of-specification process from being erroneously accepted. Comparing two separate temperature sensors will detect that one of the sensors has failed. A dual element temperature probe can be used to meet this need.

If there is an undetected failure of a control or monitoring function, a sterilization load could be released without having met its required processing parameters. To prevent this from happening, it is general practice to have redundant sensors for many critical process parameters. The common options for utilising these redundant sensors include:

a) use one sensor for control, and another sensor for monitoring and reporting;

b) use two sensors, or their average value, for both monitoring and control; this system needs to generate an automatic fault condition if the difference between the two sensors exceeds a defined value;

c) use dual element sensors for both monitoring and control; this system needs to generate an automatic fault condition if the difference between the two elements exceeds a defined value.

4.4.3 Temperature indicating instruments

In addition to the requirements in 4.4.2.1, the temperature indicating instruments shall:

a) be graduated in degrees Celsius;

b) have a scale, which includes at least 10 °C below the lowest process temperature and 10 °C above the highest process temperature;

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

d) for digital instruments have a resolution of not greater than 1 °C.

4.4.4 Pressure sensors

4.4.4.1 When used for process control, indicating or recording purposes, absolute pressure measuring instruments shall be used.

4.4.4.2 At least two independent sensors shall be used for the measurement of the chamber pressure, being dedicated to indication and recording, and control.

4.4.4.3 When used for process control, or recording purposes, pressure measuring instrument shall have maximum permissible errors of 1,5 kPa or 2,5 kPa for indicating purposes. The data sampling rate shall be high enough to ensure valid representation of the sterilization process and the response time of the sensor shall be 1 s or less.

NOTE The required sampling rate will be dependent upon the rate of change of pressure within the process. In large industrial sized chambers, the sampling rate can be every 10 s. In smaller chambers, this rate will need to be increased.

4.4.4.4 A mechanical pressure gauge shall be fitted to the sterilizer for safety reasons and shall have maximum permissible errors of 20 kPa (0,2 bar).

4.4.5 Timers and time indicating instruments

4.4.5.1 Time periods within the process shall have an uncertainty of measurement of ± 2 % or less of the process stage duration.

NOTE In some regions, the frequency of the public electrical supply is unstable and can therefore not be used to establish a time base for cycle control and recording purposes.

4.4.5.2 If dates and times are indicated, the formats dd:mm:yyyy or yyyy:mm:dd and hh:mm:ss shall be used as applicable.

4.4.6 Sterilizing cycle counter

A counter shall be provided to indicate the cumulative number of all cycles started, including those cycles in which a fault occurred. The cycle counter shall display a minimum of four digits and shall not be capable of being reset inadvertently. Additional data entry fields may be used for cycle identification.

4.4.7 Relative humidity (RH) sensors

The RH instrumentation, if fitted, shall cover the range 0 % RH to 100 % RH. In the range 30 % - 80 %, the accuracy shall be ± 10 % or better. The data sampling rate shall be high enough to ensure valid representation of the sterilization process and the response time shall be not more than 1 min. If the RH is measured it shall be recorded.

NOTE Other methods to measure humidity (e.g. gas chromatography and spectroscopy) can be used and under such circumstances, the above requirement for response time will not apply.

4.4.8 Ethylene Oxide (EO) concentration-measurement

The range for EO-concentration measurement instrument, if fitted, shall cover 0 mg/l up to 10 % over the maximum concentration specified for the process. The accuracy shall be ± 5 %. If the EO-concentration is measured, it shall be recorded.

NOTE EO-measurement is a requirement for parametric release of the load (see prEN ISO 11135:2012, 10.5).

4.4.9 Recording instruments

4.4.9.1 General

4.4.9.1.1 The recording instrumentation shall be independent from the automatic controller.

NOTE 1 This does not exclude the transfer of informative data from the automatic controller to the recorder and vice versa, via a combined system for data transfer.

NOTE 2 Sterilizer identification, cycle number and load identification can be recorded automatically.

4.4.9.1.2 For operational inspection as well as for batch documentation, analogue or digital recording instrumentation shall record pressure and temperature and, if measured, RH and EO-concentration data versus time. The records shall allow evaluation of the data for compliance with process specifications (see 9.2).

NOTE The data records can consist of digital records, analogue curves or both.

4.4.9.1.3 The recording system shall produce a record which will remain readable for a period specified by the user.

NOTE 1 The record can be printed or in electronic format.

NOTE 2 The retention period can depend on local requirements and regulations.

4.4.9.1.4 The recorder shall be either

a) a fixed and integral part of the sterilizer, or

b) as an external system connected to the sterilizer by a data link via a specified interface using specified data format.

4.4.9.1.5 If used, the data link shall allow the external system to generate records, which are compliant to all applicable specifications of 4.4.9.

4.4.9.1.6 Unless the power supply is interrupted or the instrument itself malfunctions, the instrument shall continue to operate after a fault occurs.

4.4.9.1.7 Recording instrumentation shall have a sampling interval sufficient to provide an accurate representation of the process, taking into account the dynamics of the process (see [9]).

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

4.4.9.1.9 When a fully digital system is used for recording, means shall be provided to ensure that data are secure and cannot be altered from their original state (see 5.2).

4.4.9.2 Recording instrumentation (analogue format)

4.4.9.2.1 If two or more variables are recorded in an analogue format, the displayed scale markings shall be common for all the variables recorded and the major marked interval shall be marked sequentially for each of the variables recorded.

NOTE An analogue format can be a graph and/or a chart, which can be produced either electromechanically or electronically.

4.4.9.2.2 If the recorded data are printed, the scales used shall reflect the accuracy and resolution required for the indicating instruments.

4.4.9.3 Recording instrumentation producing alphanumerical print-outs (digital format)

4.4.9.3.1 Recorders producing alphanumerical print-outs shall use alphanumeric characters and define data by text.

4.4.9.3.2 Recorders producing alphanumerical print-outs shall have a paper width with a space for a minimum of 15 characters/line.

4.4.9.3.3 Temperature recorders producing alphanumerical print-outs shall have:

— a range which includes 0 °C to 100 °C;

— maximum permissible errors of 1 °C or less over the range 20 °C to 10 °C above the highest process temperature.

4.4.9.3.4 Pressure recorders producing alphanumerical print-outs shall have:

— a range which includes 0 kPa (0 bar) to at least 10 % above the maximum process operating pressure;

— maximum permissible errors of the record of 1,6 % or less over the scale range.

4.4.9.3.5 RH recorders producing alphanumerical print-outs shall have:

— a range which included 0 % −100 %

— maximum permissible errors of 10 % over the range 30 % - 80 %

4.4.9.3.6 EO-concentration recorders producing alphanumerical print-outs shall have:

— a range which includes 0 mg/l up to 10 % over the maximum concentration specified for the process;

— maximum permissible errors ± 5 %.

4.4.10 Indicating instruments

4.4.10.1 Sterilizer instrumentation shall make available at least the following information:

a) indication of the chamber pressure;

b) indication of the chamber temperature;

c) indication of, if measured, relative humidity;

d) indication of the jacket/chamber wall temperature and pressure (if the sterilizer is fitted with a pressurized jacket);

e) indication of condition of the services (e.g. steam, nitrogen, compressed air);

f) indication of the sterilizer being in the state of alert (standby);

g) indication of sterilizer “door(s) locked”;

h) indication of the cycle selected;

i) indication of sterilizer “in progress”;

j) indication of the sterilization cycle stage;

k) indication of “cycle complete”;

l) indication of “fault” when occurring (see 5.5);

m) indication of when the sterilizer door can be opened;

n) cycle counter (see 4.4.6);

o) confirmation that gaseous EO was injected into the chamber and, if measured, an indication of it’s concentration.

NOTE The required information outlined above can be integrated into a single system or a combination of individual systems.

4.4.10.2 In addition, instrumentation at double-ended sterilizers shall provide the following visual information at the unloading side in case information a) to e) is not already displayed in the control room:

a) indication of the chamber pressure;

b) indication of sterilizer “in progress”;

c) indication of “cycle complete”;

d) indication of when the unloading door can be opened;

e) indication of “fault”.

5 Process control

5.1 General

5.1.1 The sterilizer and the sterilization cycle shall be operated by an automatic controller.

5.1.2 The sterilizer cycle shall operate with pre-set programmes. Any change of the pre-set programme or its parameters shall require the use of a key, code or tool and shall be documented.

5.1.3 The parameters of the variables programmed into the automatic controller and the tolerances that will still enable the performance requirements of Clause 6 to be met shall be specified (see also 9.2).

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

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

NOTE Widely used maximum values for the temperature and humidity in the vicinity of the control system are 50 °C and 85 % relative humidity respectively.

5.1.6 The position of the temperature sensor used to control the process shall be selected in such a way that throughout the exposure time the temperature at this point correlates with the temperature in the usable chamber volume.

5.1.7 Means shall be provided to ensure that failure in a control function does not lead to failure in recording of process parameters such that an ineffective process appears effective.

NOTE This can be achieved either by the use of independent systems for control and monitoring or by a cross-check between control and monitoring which identifies any discrepancies or indicates a fault.

5.2 Software verification and validation

5.2.1 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.

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

NOTE EN 61508–1, EN 62304 and EN 62061 can support activities to be performed.

5.3 Sterilization cycle and automatic control

5.3.1 Automatic control

5.3.1.1 The automatic controller shall be capable of being programmed with parameters and tolerances for each stage of a sterilization cycle. Programming the automatic controller shall require a special key, code or tool.

Where a cycle has been programmed for qualification purposes, the user shall have appropriate controls over it's use. Qualification cycles shall be clearly indicated.

5.3.1.2 It shall not be possible to adjust the process parameters during the progress of a sterilization cycle.

5.3.1.3 Access to control devices shall only be possible by use of a special key, code or tool.

5.3.1.4 For maintenance, test purposes and in cases of emergency, means shall be provided to permit manual progression of the automatic controller. The selection of this manual facility shall be by means of a special key, code or tool different from that specified in 5.3.1.3.

5.3.1.5 The manual advance system shall not cause a safety hazard.

5.3.1.6 On the successful completion of each specified sterilization cycle, the automatic controller shall indicate "cycle complete".

5.3.1.7 The automatic controller shall provide for reproducible sterilization cycles within the specified tolerances for each stage of the cycle.

5.3.1.8 Absolute pressure measurement systems shall be used for pressure control.

5.3.1.9 The sterilizer chamber heating system shall be provided with an over-temperature cut-out which interrupts the chamber heating in order 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.

5.3.2 Sterilization cycle

5.3.2.1 Automatic controller

The sterilizer shall perform the cycle stages given in 5.3.2.2 to 5.3.2.11 under the control of the automatic controller.

NOTE 1 Provision can be required for treatment of goods prior to sterilization to ensure that the sterilization load is heated and humidified (see prEN ISO 11135:2012).

NOTE 2 The order and number of these stages can be different from that shown below.

5.3.2.2 Chamber pre-heating/cooling

The sterilizer chamber shall be controlled to attain the pre-set working temperature. Initiation of the sterilization cycle shall not be possible until this condition has been fulfilled.

NOTE Conditioning of the sterilizer chamber could require cooling or heating, depending on the location and the process parameters.

5.3.2.3 Stage 1: Air removal

Air shall be removed from the chamber and load, sufficient to permit the subsequent attainment of sterilizing conditions.

NOTE High evacuation rate can damage the sterilization load. The vacuum rate can be dependent upon the nature of the sterilization load and is a part of the sterilization parameters.

5.3.2.4 Stage 2: Automatic Leak Rate Test

5.3.2.4.1 If the test is carried out prior to the commencement of the EO injection stage and prior to commencement of the conditioning stage, the test shall be carried out at a pre-set pressure specified by the manufacturer and agreed by the user.

NOTE 1 The automatic leak rate is a valuable indication of potential process failure and is regarded as industry best practice.

NOTE 2 The influence of the chamber temperature gradient on the chamber pressure and the degassing of the products need be taken into consideration when interpreting the results of the leak test.

5.3.2.4.2 If the pressure in the sterilizer chamber is sub-atmospheric pressure at any stage of the sterilization cycle, on attainment of the pressure specified by the manufacturer, the relevant valves shall be closed and the vacuum pump shall be stopped or isolated. The pressure rise in the chamber shall be monitored for a pre-set period of not less than 5 min, after an appropriate equilibration time allowing for a pressure stabilisation. During this period the pressure rise shall not exceed the value specified by the manufacturer.

NOTE 1 0,3 kPa/min has historically been a typical acceptance criteria.

NOTE 2 Processes operating at sub-atmospheric pressures can be vulnerable to the ingress of air. The automatic leak rate test can be an early indication of this problem.

NOTE 3 A sub-atmospheric leak test can also be provided as a separate maintenance test (see 5.3.2.12).

NOTE 4 The duration of the monitoring period and the acceptable leak rate can be dependent upon the volume of the sterilizer and the product.

NOTE 5 Initial load degassing can cause an initial pressure rise, which is not due to a chamber leak.

5.3.2.4.3 If the pressure in the sterilizer chamber is super-atmospheric pressure at any stage of the sterilization cycle, on attainment of the pressure specified by the manufacturer, the relevant valves shall be closed and the vacuum pump shall be stopped or isolated. The pressure decrease in the chamber shall be monitored for a pre-set period of not less than 5 min, after an appropriate equilibration time allowing for a pressure stabilisation. During this period the pressure decrease shall not exceed the value specified by the manufacturer.

NOTE 1 0,3 kPa/min has historically been a typical acceptance criteria.

NOTE 2 Processes operating at super-atmospheric pressures can give rise to EO emissions if the chamber leaks. The automatic leak rate test can be an early indication of this problem.

NOTE 3 The duration of the monitoring period and the acceptable leak rate can be dependent upon the volume of the sterilizer and the product.

5.3.2.5 Stage 3: conditioning (if used)

5.3.2.5.1 Means shall be provided to heat and, where necessary, humidify the load. Steam shall be used for humidification.

5.3.2.5.2 If heating and humidification are not carried out concurrently, humidification shall not precede heating.

5.3.2.5.3 The end of this stage shall be determined by elapsed time after attainment of the required temperature and humidity in the chamber.

NOTE Guidance on the determination of the time required for the humidification of load(s) is given in prEN ISO 11135:2012.

5.3.2.6 Stage 4: EO injection

Means shall be provided to ensure liquid EO will not enter the chamber. The injection rate shall be specified and controlled.

NOTE 1 The temperature of the EO gas flowing from a vaporizer to the sterilizer chamber is a means to demonstrate that gaseous EO has been produced.

NOTE 2 Gas-liquid sensors can also be used to differentiate between liquid and gaseous EO.

NOTE 3 The injection rate can be controlled actively or passively by virtue of the system design.

5.3.2.7 Stage 5: EO exposure

The chamber temperature, pressure and/or EO concentration shall be kept within the specifications during the EO exposure time. Initiation of the stage shall not occur until the pre-set levels have been attained.

5.3.2.8 Stage 6: EO removal

During this stage, EO shall be removed from the sterilizer chamber but not necessarily from the sterilization load.

5.3.2.9 Stage 7: Flushing

During this stage, EO shall be removed from the sterilization chamber and load such that the reduction in EO concentration is sufficient that the load does not present a safety hazard to the operator when the sterilizer is unloaded.

NOTE 1 This can be achieved by:

a) multiple alternate admissions of filtered air or inert gas and evacuation of the sterilizer chamber; or

b) continuous passage of filtered air or inert gas through the sterilizer chamber.

NOTE 2 The rate at which EO is removed from the load is dependent on the nature of the load, the temperature as well as the air/inert gas flow rate. There is an advantage in heating the air/inert gas to the sterilization cycle operating temperature before admission to the chamber.

5.3.2.10 Stage 8: Air admission

Air shall be admitted to the sterilizer chamber through a filter (see 4.3.8) until the sterilizer chamber pressure reaches ambient pressure.

NOTE Provision can be required to reduce further the concentration of residual EO in the load once the sterilization cycle has been completed (aeration).

5.3.2.11 Stage 9: Cycle complete

To ensure that the EO concentration in the chamber and load does not constitute a hazard, the doors shall be opened immediately at cycle complete. If this is delayed, means shall be employed to ensure the EO concentration in the chamber does not constitute a hazard when opening the unloading door.

NOTE 1 Re-evacuation of the chamber before opening the unloading door or continuous flushing can be employed.

NOTE 2 EO concentration in the chamber atmosphere varies between different product loads and different cycles. Safe concentration levels can be determined by validation.

5.3.2.12 Maintenance leak rate test cycle

5.3.2.12.1 Sterilization cycles operating at sub-atmospheric pressure

The sterilizer shall be provided with a means for leak testing the empty sterilization chamber at sub-atmospheric conditions as a tool for maintenance which shall include the sterilizer chamber and all relevant connected pipe work and fittings.

For chamber of 1 m^3 or less, the method described in Annex B shall be used to determine the chamber leak rate. In a temperature stable situation, the pressure leak rate shall not be higher than 0,1 kPa/min.

For chambers larger than 1 m^3, the leak rate parameters and acceptance criteria shall be specified.

The influence of the air leak on the safety (flammability) should be considered when establishing the allowed leak rate.

5.3.2.12.2 Sterilization cycles operating at super-atmospheric pressure

For sterilizers having a gas exposure at super-atmospheric conditions, the sterilizer shall also be provided with a means for leak testing the empty sterilization chamber at super-atmospheric conditions as a tool for maintenance which shall include the sterilizer chamber and all relevant connected pipe work and fittings.

For chamber of 1 m^3 or less, the method described in Annex B shall be used to determine the chamber leak rate. In a temperature stable situation, the pressure leak rate shall not be higher than 0,1 kPa/min.

For chambers larger than 1 m^3, the leak rate parameters and acceptance criteria shall be specified.

The influence of the air leak on the environment should be considered when establishing the allowed leak rate.

5.4 Override of automatic control

5.4.1 For maintenance, test purposes and in cases of emergency, means shall be provided to permit manual progression of the automatic controller, requiring a special key, code or tool and only allow cycle advancement to a safe state.

NOTE Additional requirements regarding intervention safety and environmental aspects are specified in EN 61010–2–040 2005 (see e.g. 13.1.101, 13.1.102, 13.101, 14.103 and 14.104).

5.4.2 If an operator selectable control or other means to abort a sterilization cycle is provided, its use shall cause a fault to be indicated.

5.5 Fault

5.5.1 If a fault is caused by a service failure (steam, air, nitrogen, or power), the requirements in 5.5.2 to 5.5.8 shall apply after restoration of the service.

5.5.2 If the value(s) for one or more of the process variables are outside the limits specified (see 5.3.2) or a failure of a service occurs sufficient to prevent the attainment of these values, the automatic controller shall:

a) cause an audible and/or a visual indication that a fault has occurred;

NOTE EN 61010–2–040: 2005 can require both in some cases (see e.g. EN 61010–2–040:2005, 13.1.101.2 and 13.1.103.3).

b) stop its normal sequential switching from the process stage to the next;

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

5.5.3 If a fault occurs before EO-injection, the automatic controller shall permit automatic progress to the sterilant removal stage and flushing with no indication of “cycle complete”.

5.5.4 The visual display indicating that a fault has occurred shall continue at least until the release of the loading door locking mechanism.

5.5.5 If a fault occurs after the EO injection has been started, the automatic controller shall ensure that the sterilizer chamber door(s) cannot be opened until it has been brought to a condition that presents no hazard to the operator or ancillary equipment.

5.5.6 The indication of a fault shall be easily distinguishable from the indication of an acceptable cycle.

NOTE This can be achieved by using different font colours or type font or highlighting.

5.5.7 After completion of a faulty cycle, access to the sterilizer load shall require the use of a key, code or tool.

5.5.8 Control systems shall have a function which causes a fault to be indicated if a sensor fails.

5.5.9 Any fault shall be recorded.

5.5.10 All fault conditions shall be tested.

5.5.11 Means shall be provided to allow fault diagnosis for maintenance purposes.

NOTE This can be done either by a diagnostic function integrated into the sterilizer control system or by allowing connection to an external diagnostic system.

6 Performance requirements

6.1 Sterilizing performance

6.1.1 Loading configuration

The sterilization load shall be introduced in the usable chamber volume in a configuration which ensures adequate circulation of gasses used during the sterilization process.

Consideration shall be given to the influence of controlled heated, cooled and unheated surfaces on the sterilization load.

The sterilization load shall not come into contact with chamber and/or other heated or cooled surfaces.

NOTE For example, heated surfaces can dehydrate the load prior to sterilant injection.

6.1.2 Physical parameters

6.1.2.1 Heating of the sterilizer chamber internal surfaces

When tested as described in C.1, the temperature of all internal surfaces shall be at the set-point temperature for the EO exposure stage ± 5 °C.

6.1.2.2 Temperature profile for an empty sterilizer chamber

When tested as described in C.2, a recorded temperature range within an empty sterilizer chamber during the EO exposure stage of less than or equal to ± 3 °C of the average recorded temperature shall be obtained.

6.1.2.3 Pressure profile

The measured pressure profile shall be compared with corresponding cycle specifications stated by the manufacturer.

NOTE Cycle development is described in prEN ISO 11135:2012, Clause 8.

6.1.2.4 Sterilant

The control parameters for the supply of EO to the process as stated in the cycle specification shall be achieved reproducibly within the pre-set values and tolerances.

NOTE 1 Examples of control parameters for supply of EO include temperature, partial pressure, concentration and weight.

NOTE 2 Systems that use premeasured single-use disposable EO cartridges are controlled by the premeasured amount of EO in the process vacuum, and the vaporizer temperature.

6.1.3 Microbiological efficacy

When tested in accordance with Annex D, the sterilization cycle shall demonstrate sufficient microbiological efficacy. Microbiological PQ can replace the test described in Annex D to show microbiological efficacy.

NOTE 1 Annex D is mostly used for serial produced EO-sterilizers, typically used in health care facilities.

NOTE 2 The testing described in Annex D cannot replace PQ as specified in prEN ISO 11135:2012.

6.2 EO removal (flushing)

The flushing stage of the cycle shall ensure that the maximum stipulated concentration of EO released into the immediate work environment, in which personnel are working without suitable protective equipment, will not be exceeded when the load is removed from the sterilizer.

NOTE In many countries national regulations exist, limiting EO concentration in air. These regulations restrict emission of EO to air from EO sterilizers.

6.3 Aeration

If aeration is carried out in the sterilizer chamber, it shall reduce the residual level of EO in the sterilized product to the levels specified in EN ISO 10993-7:2008, 4.3.

NOTE 1 Desorption of EO from the product depends on the characteristics of the product, packaging and the contents of the load.

NOTE 2 Aeration can be performed in the sterilizer chamber or in a separate aeration chamber/room.

7 Sound power

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

7.2 If equipment produces noise (except alarms) at a level which could cause a hazard, means shall be provided to reduce the risk. A-weighted sound power and emission sound pressure levels can be determined and specified for each type of sterilizer. For testing and calculation EN ISO 3746:2010 shall apply.

8 Packaging, marking and labelling

8.1 The packaging of the sterilizer and/or the sterilizer components shall be designed to protect the sterilizer and/or components and maintain its characteristics during intended transport, storage and installation.

NOTE Sterilizer and packaging design are elements that either individually or collectively provide protection against transport challenges.

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

8.3 The equipment shall be marked in accordance the regulatory requirements of each pertinent directive.

8.4 Markings and labels shall be permanently and legibly marked.

NOTE For markings regarding safety and environmental aspects, see EN 61010–2–040:2005, Clause 5.

8.5 Other permanent and legible markings shall include at least:

a) name/company and address of the manufacturer in the form of:

- street/road;
- number/house/floor;
- postal code;

— city;

— state/region;

— country;

b) name and address of authorized representative within the European Union in the case where the manufacturer does not have a registered place of business in the community;

c) the CE-mark accompanied by the European registration number(s) of the notified body or bodies engaged in the conformity assessment procedure for medical device and pressure equipment as applicable;

d) unique identification number;

e) model identification;

f) production year;

g) for manual operated sterilizer doors, instructions describing the manual action required to operate the door;

NOTE 1 These instructions can be displayed on the door, adjacent to the door, or on the operator's control panel.

h) symbols/marking labels for indicating and operating instruments;

NOTE 2 The explanation of such symbols/labels can be included in labelling or attached in user instructions.

i) control valve identification.

9 Information to be supplied by the manufacturer

9.1 Information shall be set up considering the technical knowledge, education and training of different operator categories addressed.

NOTE For guidance on information to be supplied by the manufacturer, see EN 1041.

9.2 Before installation of the sterilizer, at least the following information shall be provided to the purchaser:

a) installation instructions including overall dimensions and overall mass of the sterilizer as well as the clearance required for operational and maintenance access to the sterilizer;

NOTE 1 Additional space can be required for loading and unloading operation.

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

c) details of EO required for the sterilization, including composition;

d) dimensions of the usable chamber volume and/or the loading capacity of the sterilizer;

e) the maximum sound power levels generated by the sterilizer and any associated equipment, expressed as an A-weighted sound power level;

f) details of the pre-programmed cycle(s) and their application;

g) declaration of compliance with the EMC requirements;

h) notification that national legislation about limitations on EO concentration in air at the working place may exist (see also Annex E);

i) any restriction for installation or operation (e. g. due to EMC properties);

j) instructions for handling during transport and storage such as conditions for stability, orientation, temperature humidity and pressure;

k) further details of equipment installation for safety as required by EN 61010–2–040:2005, 5.4;

l) ambient lighting and appropriate lighting of maintenance areas;

NOTE 2 Guidance for lighting is provided in EN 1837.

m) instructions for disposal of the sterilizer packaging;

n) the permissible pressure and temperature range for the operating environment;

o) CE conformity declaration according to Directive 94/9/EC (ATEX) (see [2]).

NOTE 3 Reference can be made to ATEX [2] for processes which use EO-concentrations above 2,4 % in air or 8 % in inert gas atmosphere (TRGS 513 [11]).

9.3 Before installation qualification at least the following information shall be provided:

a) user instructions including at least:

1) identification of sterilizer manufacturer;

2) the CE-mark including, if applicable, the notified body identification number indicating the sterilizer as being a medical device;

3) general description of the field of application with available sterilization cycles (if specified by the manufacturer), including values and tolerances for the process parameters for which efficacy and safety has been established (see also 5.1.3);

4) details of pre-heating time of the sterilizer chamber required to obtain operational condition of the sterilizer;

5) characteristics of consumables and accessories dedicated to the sterilizer;

NOTE 1 This can include instructions for disposal.

6) internal dimensions of the sterilizer chamber;

7) description of controls as well as indicating, operating and recording instruments;

8) instructions for the actions to be taken in case of malfunctions;

9) instructions for daily/regular cleaning and other maintenance if required;

10) details of tests to be used at normal operation of the sterilizer and the frequency at which they should be carried out;

NOTE 2 Determination of frequency and extent of validation, routine control and requalification of the sterilizing ability is not a part of the sterilizer documentation. National guidance can exist on this topic.

11) brief description of safety devices;

12) further details of equipment operation for safety as required by EN 61010–2–040:2005, 5.4;

13) instructions for loading;

14) date of issue or date of latest revision of the instructions.

b) operating instructions;

c) maintenance manual including at least:

1) specific maintenance including specified intervals;

2) safety device checks and settings;

3) wiring and piping diagrams;

4) guidance for service and recommended spare parts.

NOTE 3 Regular maintenance is essential to preserve the performance and safety of the sterilizer as well as to ensure continuous low EO emissions.

d) manufacturer's declaration on conformity with this European Standard;

e) specifications of services and EO required [see 9.2 c)];

f) the location of the temperature sensor used for process control;

g) cleaning instructions for the chamber and the exterior including the type of agents to be used;

h) further details of equipment maintenance for safety as required by EN 61010–2–040:2005, 5.4.

9.4 The brief operating instructions shall be provided with a protective cover suitable for posting if this information is not permanently and legibly fixed on the sterilizer [see 9.3 b)].

9.5 To avoid safety-related characteristics and declared CE-conformity being jeopardized, accompanying documents shall notify that maintenance or modifications of the sterilizer shall be carried out by persons authorised by the party that has placed it on the market. If approvals for spare parts, consumables and accessories are essential for the safety or function of the sterilizer, this shall be additionally stated.

10 Service and local environment

10.1 General

The user shall be informed about requirements for installation site services that are not a part of the sterilizer [see 9.2 b)].

NOTE 1 The performance of a sterilizer is dependent upon its design and construction together with the quality of services provided.

NOTE 2 To reduce the risk of hazards to the user, it is the responsibility of the user to understand, implement, and verify all installation requirements provided by the sterilizer manufacturer.

Sterilizers complying with this European Standard shall operate with services meeting the following requirements.

10.2 Electricity

Electrical supply system, configuration, voltage, including minimum and maximum values, and connected power shall comply with the specifications provided for the sterilizer [see 9.2 b)].

10.3 Sterilant

10.3.1 EO shall be supplied either as a mixture or as a 100 % gas from a tank, cylinder or cartridge.

NOTE Cylinder and tanks provide EO for multiple processes, whereas cartridges provide a single defied measure of EO for one cycle.

10.3.2 Processes employing EO, mixed with a diluent, shall ensure homogeneous distribution of EO throughout the chamber (see also 10.4.2).

10.3.3 The design of the sterilizer shall not require the EO cylinders or tanks to be subjected to direct heating.

NOTE Direct heating is not applicable to single-use, single dose cartridges.

10.3.4 Provision shall be made to ensure that sufficient EO is available for a complete sterilization cycle.

10.3.5 The EO supply line from each EO cylinder shall include a valve to allow the supply to be automatically turned on or off.

10.3.6 An indicator shall be provided to indicate which EO cylinder is being used to supply the sterilizer chamber.

10.3.7 If no other means of confirming EO concentration in the sterilizer chamber during EO exposure is provided, each EO cylinder shall be located on automatic scales with sufficient measuring capacity for the largest size EO cylinder to be used and able to determine the mass of EO admitted to an accuracy of ± 5 % or better of the mass of EO required to fill the unloaded sterilizer chamber to the pre-set operating pressure. The information from the scales shall be inputted into the process control and data acquisition. The scales shall be used as an input device in the provision of an automatic change-over facility. Another option is to use a pre-measured quantity of EO for each cycle.

NOTE It is desirable for recording scales to be used, since the data obtained are of value in routine monitoring of the sterilization cycle.

10.4 Circulation systems

10.4.1 Forced circulation systems, if fitted, shall be provided with an indication of the satisfactory operation of the chamber gas circulation system. Failure to attain satisfactory operation shall cause a fault.

10.4.2 It shall be demonstrated that the forced circulation system, if fitted, does create homogeneous temperature and humidity distribution within the chamber during the process.

NOTE 1 This can be demonstrated by using flow measurements.

NOTE 2 Forced circulation could be needed in order to achieve homogeneous distribution of temperature and humidity (if close to the dew point) in the chamber. For pure EO cycles it is not required to have forced circulation to achieve homogeneous concentrations. If gas mixtures or inert gasses are used then forced circulation can be required to achieve homogeneous concentrations.

10.5 Steam

10.5.1 Steam shall be used to humidify the product. Steam generated by a dedicated steam supply or steam from an external supply may be used.

If boiler additives are used during steam generation, consideration should be given to potential contamination of steam used for humidification.

NOTE Potable water is considered the minimum requirement for the generation of steam for this application.

10.5.2 The quality of steam required for the process shall be according to specifications. The quality of steam shall be suitable for its intended use with equipment and product to be sterilized

10.5.3 The sterilizer shall be designed to operate with the water for the generation of steam used to humidify the chamber which is free from contaminants which can impair the sterilization process, or cause deterioration in the materials of construction of the sterilizer or cause deterioration of the sterilization load.

10.5.4 Direct injection of nebulised water shall not be used for humidification.

10.6 Water

10.6.1 Provision shall be made to ensure that water which can contain EO cannot contaminate the public supply.

NOTE Attention is drawn to the possible existence of local requirements for the maximum quantities of EO that can be discharged in effluent water.

10.6.2 Water to be used for other purposes than generating steam shall be of a quality appropriate for its intended use.

NOTE It is recommended that the water supply is fitted with a backflow protection device. For connections to potable water supply and draining, national or local regulations can apply.

10.7 Air and inert gasses

Air which can come into contact with the load shall be produced or treated to ensure that it is dry, free from oil and filtered (see 4.3.8.1).

Air and inert gases admitted to the chamber during the sterilization cycle shall be filtered (see 4.3.8.1).

10.8 Drainage and discharges

Additional requirements for drainage facilities shall be specified [see 9.2 b) and 10.1].

NOTE 1 National regulations specify basic design requirements including a backflow protection.

NOTE 2 EN 61010–2–040:2005, 13.1 including following subclauses, includes additional requirements for drainage and discharges affecting safety and environmental aspects [see 9.2 k)].

10.9 Ventilation and environment

The operating conditions for the sterilizer (temperature and humidity) shall be specified.

10.10 Lighting

The sterilizer shall be designed to operate with a minimum external illumination of 200 lx.

Annex A
(normative)
Test instrumentation

The specification for external temperatures, pressures and humidity measuring equipment shall be:

— inaccuracy $T \leq 0{,}5$ °C;

— inaccuracy $P \leq 0{,}5$ kPa;

— Data sampling rate 1 s or less;

NOTE In some instances, tests can be carried out using self-contained data loggers. In such instances, the data sampling rate will need to be adjusted to allow for memory capacity, whilst not compromising the need to record a valid representation of the process.

— response time of temperature and pressure sensors ≤ 1 s;

— test equipment of RH, a range 0 % to 100 % with an inaccuracy of ≤ 10 %, Response time for RH ≤ 10 s.

Presentation of recordings, analogue or digital, should at least be able to read the given requirements.

Annex B
(normative)
Leak test cycle

NOTE These tests are intended to be used as maintenance test cycle (see 5.3.2.12).

B.1 If the pressure in the sterilizer chamber is below atmospheric pressure at any stage in the sterilization cycle, the sterilizer shall be provided with a leak test cycle under the control of the automatic controller (see 5.3). If the pressure in the sterilizer chamber is above atmospheric pressure at any stage in the sterilization cycle, the sterilizer shall be provided with a leak test cycle under the control of the automatic controller (see 5.3.2). Selection of this operating cycle shall only be accessible by means of a special key, code or tool.

B.2 Selection of this operating cycle shall initiate the following sequence of operations:

a) for cycles where the pressure is below atmospheric pressure, reduction of the pressure in the sterilizer chamber or the air removal stage set pressure, whichever is the lower, to 15 kPa; For cycles where the pressure is above atmospheric pressure increase the pressure to the highest pressure observed during the sterilization cycle using nitrogen or dry compressed air;

b) close the relevant valves;

c) stop or isolate the vacuum pump;

d) allow a (300 ± 10) s stabilisation period;

e) maintenance of the sterilizer chamber in this condition for a pre-set period of not less than 900 s;

NOTE This test is intended to establish the integrity of the chamber and associated equipment. For the purposes of environmental protection and workers safety, the leak rate test can be carried out over a much longer period to satisfy national requirements.

f) admission of air after this period to the sterilizer chamber through the filter until the sterilizer chamber pressure is within 10 kPa of ambient.

B.3 There shall be an indication, visible to the operator, when the leak test timer is operating.

B.4 At the end of a leak test cycle the automatic controller shall indicate that a leak test cycle has been selected and performed.

NOTE The test is used for type testing and can also be used following installation, changes to the equipment that could influence the gas tightness and can also be used during routine maintenance.

Annex C
(normative)
Sterilizer chamber profile testing

C.1 Sterilizer chamber internal surfaces

C.1.1 A homogeneous temperature distribution of all heated internal surfaces shall be demonstrated. The temperature of the representative regions of the internal surfaces shall be measured and recorded using a temperature recorder complying with the requirements of Annex A.

C.1.2 Not less than one measurement shall be made on each heated internal surface (i.e. a minimum of six thermocouples when six heated surfaces are available). At least one temperature sensor shall be used for every 5 m^2 surface area of the chamber.

C.1.3 The test shall be carried out with the sterilizer chamber empty of any load but containing any load handling equipment normally present during a sterilization cycle, with the doors closed.

C.1.4 Temperatures shall be recorded after any pre-heating stage specified by the manufacturer.

C.1.5 The location where each measurement is made shall be documented.

C.1.6 The test shall be carried out with the chamber heating control system on, under atmospheric pressure for a period not less than the longest cycle time in use for that set temperature.

NOTE The sterilizer can be in standby mode for this test.

C.2 Empty sterilizer chamber

C.2.1 The temperature and RH of representative regions of the usable sterilizer chamber space and pressure shall be measured and recorded using measuring instrument(s) complying with the requirements of Annex A.

C.2.2 The number of temperature sensors to be used shall be in accordance to prEN ISO 11135:2012, Table C.1.

Care should be taken that those regions of the usable sterilizer chamber space likely to show extreme variations of temperature e. g. close to unheated portions of the chamber door, close to steam entry points, are included.

C.2.3 The test shall be carried out with the sterilizer chamber empty of any load, but containing any load handling equipment normally present during a sterilization cycle, with the doors closed.

C.2.4 The location where each measurement is made shall be documented. The temperatures in the sterilizer chamber shall be measured and recorded throughout a normal sterilization cycle.

NOTE 1 For the purpose of this test, EO can be replaced with a suitable non-toxic, non-flammable gas or gas mixture admitted to the chamber through the EO supply system (including the vaporiser).

NOTE 2 Performing humidity testing in conjunction with temperature testing provides correlation between differential pressure and relative humidity.

Annex D
(normative)
Microbiological test for EO sterilizers

D.1 General

This test is designed to demonstrate that under the defined test conditions the sterilizer is capable of achieving microbiological inactivation. This test shall not replace microbiological PQ (see prEN ISO 11135:2012). PQ can replace this test.

NOTE 1 Attainment of sterilization conditions within actual loads is determined by validation and verified for each cycle by routine control and monitoring. Requirements and guidance for the validation and routine control of EO sterilization are given in prEN ISO 11135:2012.

NOTE 2 Inactivation will already occur during EO injection and initial re-vacuum stage, which is to be considered when performing microbiological testing.

D.2 Test equipment

NOTE Regulations and environmental effects of the disposal of used chemicals and indicators are subjects to be investigated and planned prior to use.

D.2.1 At least four process challenge devices (PCDs) selected (see note) as specified for this specific sterilizer design and process.

NOTE A number of process challenge devices have been specified for the microbiological evaluation of EO sterilization processes. Examples include, but are not restricted to:

— The Line Pickerel Helix. This PCD was first reported by Line S J and Pickerel J [7].

— The biological indicator challenge test pack. This process challenge device is specified in ANSI - AAMI ST41.

— The industrial biological indicator process challenge device. This PCD consists of a biological indicator sealed within a polymer bag of specified material, grade and thickness.

— The customised biological indicator process challenge device. This PCD is bespoke for a specific application and is specified by the manufacturer.

D.2.2 Sterile barrier systems shall comply with EN ISO 11607-1, EN 868-4 and EN 868-5.

D.2.3 Biological Indicators shall comply with EN ISO 11138-1 and EN ISO 11138-2.

D.2.4 Appropriate recovery media for the biological indicators.

D.2.5 An incubator, which is set at the temperature specified for the biological indicator.

D.3 Procedure

D.3.1 Select the sterilization cycle to be tested.

D.3.2 Prior to use condition the specified PCD in an atmosphere of 20 °C to 30 °C and 40 to 60 %RH for not less than one hour. For PCD's having hollow lumen the atmosphere within the lumen should be purged with air at 20 °C to 30 °C and 50 % to 60 % RH.

For reusable PCD's the conditioning procedure needs to be capable of desorbing any residual EO from the material of construction to a level no longer deemed to be microbicidal, removing any residual moisture absorbed, adsorbed or retained within the PCD and returning the temperature of the PCD to the conditions specified above.

D.3.3 Place one biological indicator at the specified point within the process challenge device and seal into position.

NOTE For example for PCD's based on helixes this will be the capsule at the blind end of the specified lumen.

D.3.4 Package each PCD in the sterile barrier system selected,

D.3.5 Package each of four biological indicators in the sterile barrier system selected.

D.3.6 The packaged process challenge devices and packaged biological indicators shall then be subjected to the specified sterilization process to include, the process stages specified in 5.3.2.1.

D.3.7 The EO exposure time shall be sufficient to inactivate the BI chosen.

D.3.8 Run the cycle specified in D.3.7.

D.3.9 At the end of the cycle, remove the PCDs and biological indicators from the sterilizer.

NOTE A reduced flushing and aeration stage can be used provided it can be shown that residual EO levels are below the limits allowable for safe handling of processed goods.

D.3.10 Using aseptic conditions where necessary, remove the biological indicators from the PCD and packaging and subject them to the recovery procedures specified by their manufacturer and examine for compliance with 6.1.2.

D.3.11 Subject an unexposed biological indicator from the same batch as used in the test to the recovery conditions specified by their manufacturer. The presence of viable microorganisms shall be indicated or the test shall be regarded as invalid and repeated.

D.3.12 Repeat the test a further two times.

D.4 Interpretation of results

D.4.1 Confirm that the process met the cycle specifications.

D.4.2 Confirm inactivation of all BIs exposed to the process.

D.4.3 If the process met the cycle specification and all BIs were inactivated, the microbiological capabilities of the EO-sterilizer has been demonstrated.

If the process did not meet the cycle specifications or not all BI's were inactivated, the cause shall be investigated, corrected and the test shall be repeated.

D.4.4 Document the result of the test.

Annex E
(informative)
Environmental aspects

E.1 Environmental aspects regarding the life cycle of EO sterilizers

Environmental aspects covered by this European Standard are summarised in Table E.1.

E.2 EO (brief description)

EO is a colourless, odourless, toxic gas, carcinogenic, explosive and highly soluble in water. Attention is drawn to the possible existence in some countries of regulations giving safety requirements for handling EO and for premises in which it is used.

NOTE 1 EO or as EO mixtures with other gases, can be explosive depending on the concentration.

NOTE 2 Epidemiologic studies have shown that exposure to accepted limits [8 hr. time weighted average (TWA)] of EO does not appear to present a health hazard.

E.3 Environmental impact

The potential effect on the environment of the operation of the sterilization process should be assessed and measures to protect the environment should be identified. This assessment, including potential impact and measures for control, should be documented.

Users of EO should comply with applicable local, national and international requirements regarding the emission and disposal of EO and its diluents.

Table E.1 — Environmental aspects addressing clauses of this standard

Environmental aspects (Inputs and Outputs)		Product life - cycle			
		Production and reproduction **Stage A**	**Distribution (including packaging)** **Stage B**	**Use** **Stage C**	**End of life** **Stage D**
		Addressed in clause	Addressed in clause	Addressed in clause	Addressed in clause
1	Resource use	Introduction 4.3.6	-	Introduction 4.3.4 4.3.6	-
2	Energy consumption	Introduction 4.3.6	-	Introduction 4.3.6 9.2 10.2	-
3	Emission to air	Introduction	-	Introduction 4.2.2.10 4.3.4.2 4.3.9 5.3.2.4 6.2 9.2 10.8 Annex B E.3	Introduction 9.2

4	Emission to water	Introduction	-	Introduction 4.3.4 4.3.9 9.2 10.6 E.3	Introduction 9.2
5	Waste	Introduction D.4	9.2	Introduction 9.3 E.3	Introduction 9.2
6	Noise	-	-	7 9.2	-

Annex ZA
(informative)
Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

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

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

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

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.1, 4.2, 4.3, 4.4, 5.1, 5.3, 5.4, 5.5	7.2	
4.1, 4.3	7.3	
4.1, 4.2, 4.3, 4.4, 5.1, 5.3, 5.4, 5.5	7.5 (1)	
4.1, 4.2, 4.3, 5.1, 5.3, 5.5	7.6	
4.2, 4.3, 5.1, 5.3, 5.4, 5.5, 6.1, Annex D	8.1	
4.3.12, 8.1, 8.2, 9.2	8.6	
4.1, 4.3, 4.4, 6.1, 9.3, 10.3	9.1	
4.1, 4.2, 4.3, 5.1, 9.2, 9.3, 10.9	9.2	
4.1, 4.2, 5.1, 5.3, 5.5, 9.2, 10.3	9.3	
4.4, Annex A	10.1	
4.4, Annex A	10.2	
4.4, Annex A	10.3	
4.3.7, 9.2	11.1	
4.3.7, 9.2	11.3	
4.1, 4.3, 4.4, 5.1, 5.2, 5.5	12.1	
4.3.7, 9.2	12.5	
4.3.7, 5.5, 9.2	12.6	
4.2, 4.3, 5.5	12.7.1	
7, 9.2	12.7.3	
	12.7.4	The user is not expected to handle terminals and connectors to the

		electricity, gas or hydraulic and pneumatic energy supplies
4.3	12.7.5	
4.4, 5.1, 5.3, 6.1.2.4	12.8.2	
4.2, 4.4, 8.5, 9.1, 9.3, 9.4	12.9	
8.2, 8.5, 9.1, 9.2, 9.3	13.1	
8.5	13.2	Partially addressed, no requirements for symbols.
8.5	13.3 a)	Partially addressed, no specific requirements for labels.
8.5	13.3 b)	
8.5	13.3 d)	
8.2	13.3 i)	
	13.3 j)	Not on label but in instructions for use
	13.3 k)	Not on label but in instructions for use
8.5	13.3 l)	
	13.5	Marking of detachable components not addressed.
9.2, 9.3	13.6 a)	Partially addressed, details to identify device not addressed.
9.3	13.6 b)	
	13.6 c)	
9.2, 9.3	13.6 d)	
9.2	13.6 f)	
9.3	13.6 k)	
9.2, 9.3	13.6 l)	Partially addressed, allowed conditions EMC-compatibility and routine checks are specified, but no precautions for environmental conditions given.
9.2	13.6 n)	
9.3	13.6 p)	
9.3	13.6 q)	

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

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

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

Clause(s)/sub-clause(s) of this EN	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
4.3	1.1.3	
9.2, 10.10	1.1.4	
4.3, 8.1, 8.2, 9.2	1.1.5	
4.3, 5.1, 5.2, 5.4, 9.1, 9.3	1.1.6	
6.2, 9.2, 9.3, 10.3	1.1.7	
4.3, 5.2, 5.3, 5.5, 6.2, 10.9	1.2.1	
4.2, 4.4, 5, 9.3	1.2.2	
4.2, 4.4, 5, 9.3	1.2.3	
4.2, 4.4, 5, 9.3	1.2.4	
4.2, 4.4, 5, 9.3	1.2.5	
4.3, 5.5, 10.2	1.2.6	
4.3, 9.2	1.3.1	
4.1, 4.3, 5.5, 9.3	1.3.2	
4.3, 9.2	1.3.3	
4.3	1.3.4	
4.2, 4.3, 9.2, 9.3	1.3.7	
4.3	1.3.8	
4.3, 5.5	1.3.9	
4.3	1.4.1	
4.3	1.4.2	
4.3	1.4.3	
4.3	1.5.1	
4.3	1.5.2	
4.3	1.5.3	
4.1, 4.2, 4.3, 9.2, 9.3	1.5.4	
4.1, 4.3	1.5.5	
4.1, 4.3, 5.3	1.5.6	
4.1, 4.3, 5.3, 9.3	1.5.7	

4.1, 4.3, 5.5, 6.2, 10.8, 10.9	1.5.13	
4.3	1.5.14	
4.2, 4.3, 5.3, 5.4, 9.1, 9.3	1.6.1	
4.2, 4.3, 4.4, 5.3, 5.4, 9.1, 9.3	1.6.2	
4.3	1.6.3	
4.4, 5	1.6.4	
4.2, 4.3, 9.3	1.6.5	
4.3, 4.4, 8.3, 8.4	1.7.1	

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

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