BS EN 14180:2014

BSI Standards Publication

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

bsi.

...making excellence a habit.™

National foreword

This British Standard is the UK implementation of EN 14180:2014. It supersedes BS EN 14180:2003+A2:2009 which is withdrawn.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.

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

Published by BSI Standards Limited 2014

ISBN 978 0 580 78885 7
ICS 11.080.10

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

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 May 2014.

Amendments/corrigenda issued since publication

Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 14180

May 2014

ICS 11.080.10

Supersedes EN 14180:2003+A2:2009

English Version

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

Stérilisateurs à usage médical - Stérilisateurs à la vapeur et au formaldéhyde à basse température - Exigences et essais

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

This European Standard was approved by CEN on 10 April 2014.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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

CEN members are the national standards bodies of 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 United Kingdom.

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

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

Contents

Page

Foreword

This document (EN 14180:2014) 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 November 2014.

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 14180:2003+A2:2009.

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(s).

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

The standard is a full technical revision of the previous version. The following amendments have been made in comparison to EN 14180:2003+A2:2009:

— normative references were updated;

— terms risk assessment, risk analysis and software validation were added;

— align biological testing with method from EN ISO 25424;

— requirements for heat isolation were updated;

— safety requirements, mainly as a consequence of compliance with the machinery directive were added;

— requirements and testing for sound power, also including vibration, were updated;

— Annex ZA including Tables ZA1 and ZA2 were updated.

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

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

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

LTSF processes are specified by physical parameters and verified using physical, chemical and microbiological means [8]. The sterilizers operate automatically using pre-set cycles.

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

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

At the present state of knowledge, LTSF sterilizers should not be assumed to deliver processes effectively inactivating the causative agents of spongiform encephalopathies such as scrapie, Bovine Spongiform Encephalopathy and Creutzfeld-Jakob Disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents. See also EN ISO 25424:2011, 1.2.1.

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

NOTE Specifications on operator safety are addressed in EN 61010–1, EN 61010–2–040 and are not repeated in this standard. EN 60204–1 can also give valuable guidelines.

1 Scope

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

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

This European Standard specifies minimum requirements:

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

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

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 867–5, *Non-biological systems for use in sterilizers - Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S*

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 14222:2003, *Stainless steel shell boilers*

EN 60584–2, *Thermocouples — Part 2: Tolerances*

EN 60751:2008, *Industrial platinum resistance thermometers and platinum temperature sensors (IEC 60751:2008)*

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 61326-1:2013, *Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 1: General requirements (IEC 61326-1:2012)*

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

EN ISO 1874-1, *Plastics - Polyamide (PA) moulding and extrusion materials - Part 1: Designation system and basis for specification (ISO 1874-1)*

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

EN ISO 11138-1:2006, *Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2006)*

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

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

EN ISO 15223-1, *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1)*

3 Terms and definitions

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

3.1
access device
means used to enable access to restricted parts of equipment

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

3.2
aeration
part of the sterilization process during which sterilizing agent 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.

3.3
air removal
removal of air from the sterilizer chamber and sterilization load to facilitate sterilant penetration

3.4
automatic controller
device that, in response to cycle parameters, operates the apparatus sequentially through the operating cycle(s)

3.5
biological indicator
test system containing viable microorganisms providing a defined resistance to a specified sterilization process

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

3.6
chamber pre-heating
heating of inner sterilizer chamber surfaces to achieve predetermined temperatures prior to the commencement of a sterilization cycle

3.7
conditioning
treatment of product within the sterilization cycle, but prior to the holding time, to attain a predetermined temperature, humidity and, if applicable, concentration throughout the sterilization load

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

[SOURCE: EN 285:2006+A2:2009, 3.9]

3.9
cycle parameter
specified value for a cycle variable

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

3.10
cycle variable
physical property that influences the efficacy of the operating cycle

Note 1 to entry: For LTSF-sterilizers, the cycle variables include, but are not necessarily limited to temperature, pressure, time, sterilant concentration.

3.11
desorption
removal of the sterilant from the chamber and the load at the end of the exposure time

3.12
desorption indicator
indicator, intended to determine the amount of sterilant residuals

3.13
double-ended sterilizer
sterilizer in which there is a door at each end of the sterilizer chamber

[SOURCE: EN 285:2006+A2:2009, 3.11]

3.14
exposure time
period between introducing the sterilant into the chamber and the start of the desorption phase

3.15
inoculated carrier
supporting material on or in which a defined number of viable test organisms have been deposited

[SOURCE: EN ISO 11138-1:2006, 3.10]

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

[SOURCE: ISO/TS 11139:2006, 2.22]

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

[SOURCE: EN 285:2006+A2:2009, 3.17]

Note 1 to entry: See also 3.47 unloading door.

3.18
LTSF-equilibration time
period which elapses between the attainment of the sterilization temperature at the reference measurement point and the attainment of the sterilization temperature at all points within the load

3.19
LTSF - holding time
period for which the temperature at the reference measurement point and all points within the load, and further cycle variables are held within pre-set values and their tolerances

Note 1 to entry: The holding time follows immediately after the equilibration time.

3.20
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]

3.21
microbicidal solution
aqueous solution containing formaldehyde to feed the vaporiser for generating sterilant in the sterilizer

3.22
operating cycle
the automatic sequence of operating stages performed in a sterilizer

3.23
operational qualification
OQ
process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

[SOURCE: ISO/TS 11139:2006, 2.27]

3.24
operator
person operating equipment for its intended purpose

3.25
override
means intended only for maintenance or safety, by which the operating cycle can be interrupted or modified

3.26
post-cycle flushing

stage after “cycle complete” indication, during which the sterilization load is left in the closed chamber and the internal chamber atmosphere is exchanged

3.27
pressure vessel
vessel consisting of the sterilizer chamber, door(s) and other components that form a permanent unit with the sterilizer chamber and that are pressurised by the same pressure

3.28
process challenge device
PCD
item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process

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

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

3.29
reference measurement point
point where the temperature sensor used for the operating cycle control is located

3.30
requalification
repetition of part of validation for the purpose of confirming the continued acceptability of a specified process

[SOURCE: ISO/TS 11139:2006, 2.40]

3.31
risk assessment
overall process comprising a risk analysis and a risk evaluation

[SOURCE: EN ISO 14971:2012, 2.18]

3.32
risk control
process in which decisions and measures are implemented by which risks are reduced to, or maintaining risks within, specified levels

[SOURCE: EN ISO 14971:2012, 2.19]

3.33
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: EN ISO 9000:2005, modified.3.34.

3.34
sterilant
microbicidal agent composed of steam containing formaldehyde

3.35
sterilant injection
single or repeated stage beginning with the introduction of sterilant into the evacuated sterilizer chamber and ending when the set operating pressure has been attained

3.36

sterile
free from viable microorganisms

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

3.37
sterilization
validated process used to render product free from viable microorganisms

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

[SOURCE: ISO/TS 11139:2006, 2.47]

3.38
sterilizer
equipment designed for the purpose of sterilization

3.39
sterilizer chamber
part of the sterilizer which receives the sterilization load

[SOURCE: EN ISO 17665-1:2006, 3.56]

3.40
sterilization cycle
predetermined sequence of operating stages performed in a sterilizer for the purpose of sterilization and desorption

3.41
sterilization load
product to be, or that has been, sterilized together using a given sterilization process

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

3.42
sterilization process
series of actions or operations to achieve the specified requirements for sterility

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

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

3.43
sterilization temperature
minimum temperature on which the evaluation of the sterilization efficacy is based

[SOURCE: EN 285:2006+A2:2009, 3.33]

3.44
sterilization temperature band
temperature range the minimum of which is the sterilization temperature

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

3.45
sterilizing agent
physical or chemical entity, or combination of entities having sufficient microbicidal activity to achieve sterility under defined conditions

[SOURCE: ISO/TS 11139:2006, 2.50]

Note 1 to entry: The sterilizing agent is the condensate film, generated by condensation of the sterilant on the surface of the medical devices to be sterilized.

3.46
theoretical sterilant temperature
temperature of the sterilant, calculated from the temperature versus vapour pressure relationship of the sterilant

Note 1 to entry: This value is calculated from the beginning of the exposure time until the beginning of aeration.

3.47
unloading door
door in a double-ended sterilizer through which the sterilization load is removed from the sterilizer chamber after a sterilization cycle

Note 1 to entry: See also 3.18 loading door.

3.48
usable space
specified space inside the sterilizer chamber, which is not restricted by fixed parts and which is available to accept the sterilization load

3.49
validation
documented procedure for obtaining recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications

[SOURCE: EN ISO 11139:2006, 3.35]

3.50
verification
confirmation through provision of objective evidence that specified requirements have been fulfilled

[SOURCE: EN 62304:2006, 2.55]

3.51
works test
series of tests performed prior to delivery to demonstrate compliance of each piece of equipment with its specification

4 Technical requirements

4.1 Sterilizer chamber

4.1.1 Materials

4.1.1.1 The surfaces of the materials for the pressure vessel (including, for example, welds) that can come into contact with process chemicals shall be of materials which, under the designed operating conditions, are not impaired by these chemicals. They shall not release any substances known to be toxic in such quantities that can create a health or environmental hazard.

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

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

4.1.2 Chamber size

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

a) for cylindrical horizontal or cylindrical vertical usable spaces: 000 x 000 in which:

   1) the first three digits give the diameter of the usable space; and

   2) the last three digits give the depth of the usable space;

b) for rectangular parallelepiped usable spaces: 000 x 000 x 000 in which:

   1) the first three digits give the width of the usable space;

   2) the next three digits give the height of the usable space; and

   3) the final three digits give the depth of the usable space;

c) for other configurations the usable space shall be specified in analogy to a) or b);

d) if any dimension exceeds 1000 mm then four digits shall be used, without a decimal point.

4.1.3 Doors and interlocks of the sterilizer chamber

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

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

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

4.1.3.4 In case of an interrupted cycle (e. g. due to a fault), opening of the sterilizer door e. g. to gain access to the load shall require the use of an access device.

4.1.3.5 The design shall allow easy and safe maintenance of the door seal(s) according to the instructions of the manufacturer.

4.1.3.6 For double-ended sterilizers it shall not be possible to open the unloading door until a “cycle complete” indication is obtained.

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

4.1.3.8 The control used to start the automatic operating cycle shall be located at the loading side of the sterilizer.

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

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

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

4.1.4 Heating and insulating the sterilizer chamber

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

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

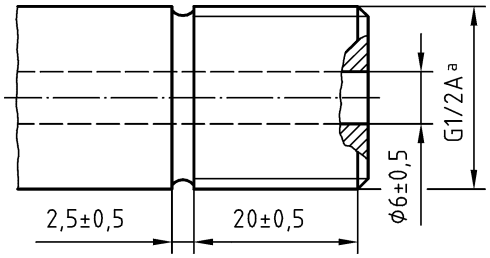
4.1.5 Test connections

4.1.5.1 The sterilizer chamber shall be provided with a test connection, which is used for the connection of a test pressure measuring instrument. This connection shall be at a point of easy access, but not in a pipe for media transport or evacuation, and shall terminate in a pipe thread ISO 228-G1/2A according to EN ISO 228-1. An example is given Figure 1.

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

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

Dimensions in millimetres



Key

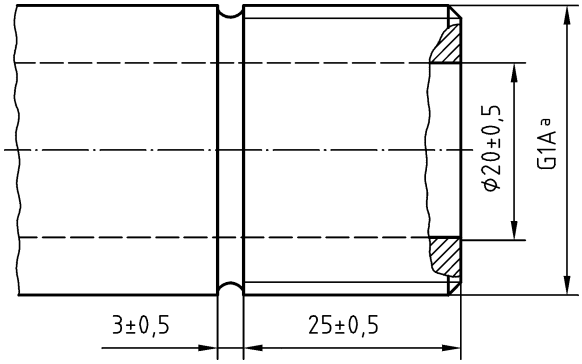
[a] pipe thread ISO 228-G1/2A

Figure 1 — Example of the connection for test instruments

4.1.5.2 The sterilizer chamber shall be provided with a straight thermometry entry connection. An example is given in Figure 2. This connection shall be at a point of easy access.

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

Dimensions in millimetres



Key

[a] pipe thread ISO 228-G1A

Figure 2 — Example of thermometry entry connection

NOTE The test connections can be provided as accessories to be attached to a single entry port of the chamber.

4.2 Design and construction

4.2.1 Risk control and usability

4.2.1.1 Risk assessment and risk control for sterilizer design and software should be performed following the procedures and requirements given in EN ISO 14971:2012, Clauses 4, 5 and 6. Specific requirements and results should be established and documented.

For products designed and placed on the market prior to publication of this edition of EN 14180 other standards may have been applied instead of EN ISO 14971.

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

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

4.2.2 Safety

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

NOTE 1 For general design related to safety 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.

4.2.2.2 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, 7.3.4, and 10.1 are exceeded.

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

4.2.2.3 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 by EN 61326-1:2013, 3.3.

The immunity performance criteria selected shall ensure that sterilizer performance as specified by 5.3 and Clause 6 of this standard is met when exposed to disturbance phenomena of EN 61326-1:2013, Table 2.

4.2.3 Pressure equipment

A Council Directive on the approximation of the laws of the member states concerning pressure equipment was released on 29 May 1997 (97/23/EC) [3] and corresponding European Standards EN 13445 (series), EN 14222 and EN 764-7 may apply.

4.2.4 Pipework and fittings

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

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

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

4.2.4.3 Pipework shall be designed to prevent accumulation of condensate.

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

4.2.4.5 All control valves in the pipework shall be marked with permanent identification in relation to their functions (see 8.4).

4.2.5 Evacuation system

4.2.5.1 Sterilizers shall be provided with a vacuum system to remove air, water and sterilant. The lowest absolute pressure needed for fulfilling the requirements of Clause 6 when tested according to A.3 shall be specified.

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

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

At leak testing the chamber and relevant pipework shall be evacuated to or below the lowest process pressure. The pressure rise shall not exceed 0,1 kPa/min over a period of not less than 5 min and not more than 15 min after obtaining the lowest pressure.

4.2.6 Aeration system

4.2.6.1 When the sterilizer chamber is ventilated during the aeration for the purpose of desorption and to release the vacuum at the end of the process, microbial recontamination of the sterilization load shall be prevented.

4.2.6.2 When a filter is fitted to the sterilizer to prevent microbial recontamination during aeration or pressure equalization, it shall be readily accessible for replacement. The filter shall be capable of retaining at least 99,5 % of particles with a diameter of 0,3 µm at a pressure difference of 1 bar and at maximum airflow.

Means shall be provided between the filter and the sterilisation chamber to prevent fluid flow from the sterilizer chamber into the filter.

4.2.7 Framework and panelling

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

NOTE 1 Side panelling is not required for sterilizers designed to be recessed into existing walls providing continuous joint with the sterilizer front panelling.

Removal or opening of panel used as 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 2 Ventilation openings can be provided in the panelling.

4.2.7.2 The panelling of the sterilizer shall allow access for maintenance work. Such panelling shall be demountable or the dimensions of any personal access shall be not less than 500 mm wide and not less than 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 shall be positioned so that it will not compromise the safety of either the product or persons.

NOTE Requirements for access are also specified in EN 61010–1:2010, 7.3.2 and 7.3.5.

4.2.8 Accessories

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

If the equipment is intended to be connected to dedicated accessories, these combinations shall not cause any hazard or detrimental effect to the performance of the sterilizer. The mutual compatibility of both systems shall be verified (see 4.2.1 and 5.2).

4.2.9 Transport

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

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

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.

4.3 Indicating, measuring, operating and recording devices

4.3.1 General

4.3.1.1 Indicating and operating devices 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.

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

4.3.1.3 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.

4.3.1.4 Indicating and operating devices shall be readable when viewed at a distance of (1 ± 0,15) m with normal or corrected vision in an illumination of (215 ± 15) lx.

4.3.1.5 Indicating, measuring and recording devices shall have means to be adjusted *in situ* by the use of an access device without dismantling the instrument. For analogue indicating instruments that are not easily demountable, means for adjustment *in situ* shall be provided.

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

4.3.1.6 Additional functions fitted at recording or indicating devices shall not jeopardize the accuracy of registration or indication.

4.3.2 Temperature measuring devices

4.3.2.1 When used for process control, monitoring or registration purposes, temperature measuring devices shall have maximum permissible errors of 1 K or less over the scale range 20 °C to 100 °C and be adjusted to ± 0,5 K or less at the sterilization temperature.

4.3.2.2 Temperature control systems shall be protected against unauthorised operation by the use of an access device.

4.3.2.3 At least two independent sensors shall be used for the measurement of the chamber temperature, being dedicated to indication, control and registration. The sensors shall be located in the most representative position in the chamber specified as being the reference measurement point.

4.3.2.4 The registration and monitoring/controlling devices shall be mutually independent as given by any of the arrangements shown in Figure 3.

4.3.2.5 The temperature sensor including the measuring system it is connected to shall have a response time $\tau_{0,9} < 5$ s when tested in flowing water according EN 60751:2008, 6.5.2.

4.3.2.6 Temperature control systems shall have a function which causes a fault to be indicated if a sensor fails.

4.3.3 Temperature indicating devices

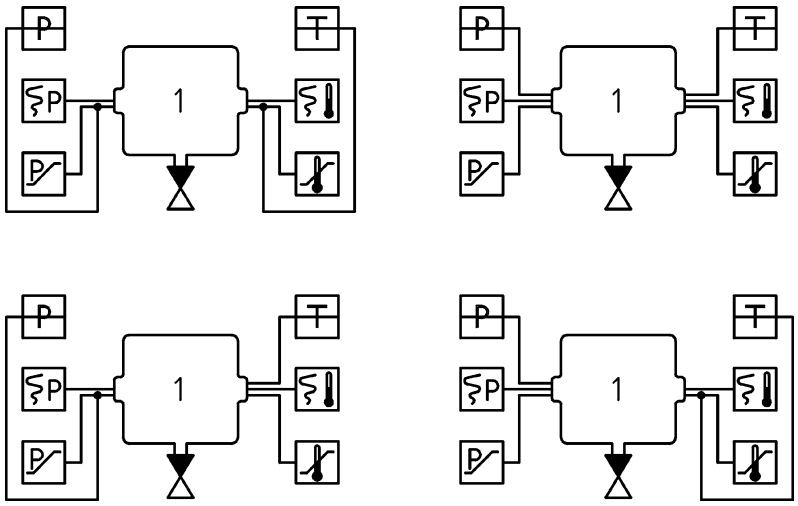
In addition to the requirements in 4.3.2.1, the temperature indicating devices shall:

— be graduated in degrees Celsius;

— have a scale, which includes 0 °C to 100 °C;

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

— for digital instruments have a resolution of at least 0,1 °C.



Key

1 chamber

Temperature indicating instrument

Temperature recorder

Temperature controller

Pressure indicating instrument

Pressure recorder

Pressure controller

Figure 3 — Arrangements for temperature and pressure sensors

4.3.4 Pressure measuring and indicating devices

4.3.4.1 When used for control, monitoring or registration purposes, pressure measuring and indicating systems shall be protected against unauthorised operation by the use of an access device.

4.3.4.2 When used for process control, monitoring or registration purposes, absolute pressure measuring systems shall be used.

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

4.3.4.4 The registration and monitoring/controlling devices shall be mutually independent as given by any of the arrangements shown in Figure 3.

4.3.4.5 When used for process control, monitoring or registration purposes, pressure measuring and indicating chain shall have maximum permissible errors of 1 % or less over the scale range, and be adjusted to ± 0,8 kPa (±0,008 bar) or less over the range from 0 kPa (0 bar) up to the sterilization pressure.

4.3.4.6 When used for process control, monitoring or registration purposes, pressure measuring systems shall have a function which causes a fault to be indicated if a sensor fails.

4.3.4.7 Pressure indicating devices shall:

— be graduated in kilopascals or bars;

— have a scale which includes the range 0 kPa (0 bar) to at least 10 % above the maximum process operating pressure when used for process control or monitoring purposes;

— have maximum permissible errors as specified in 4.3.4.5 when used for process control or monitoring purposes or have maximum permissible errors of 1,6 % or less over the scale range at others;

— for analogue instruments, be graduated in divisions not greater than 5 kPa (0,05 bar) when used for process control or monitoring purposes and in divisions not greater than 20 kPa (0,2 bar) for other purposes;

— for analogue instruments indicating overpressure, have the maximum allowable operating pressure legibly identified;

— for digital instruments, have a resolution of not more than 0,5 kPa (0,005 bar) and be adjusted to better than 0,8 kPa (0,008 bar) from 0 kPa (0 bar) to the sterilization pressure.

4.3.5 Timers and time indicating devices

4.3.5.1 A timer shall control the holding time.

4.3.5.2 Time periods within the process shall have an uncertainty of measurement of ± 1,0 s or less.

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

4.3.5.4 The time period of each time controlled part of the operating cycle shall be adjustable by the means of an access device.

4.3.5.5 Means shall be provided, independent of the process control, to verify the time period of each stage of the operating cycle.

4.3.6 Sterilizing cycle counter

A counter shall be provided to indicate the cumulative number of all operating 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 or deliberately.

4.3.7 Recording instruments

4.3.7.1 General requirements

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

NOTE 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.

4.3.7.1.2 For operational inspection as well as for batch documentation, analogue or digital recorders shall record pressure and temperature data versus time. The records shall allow evaluation of the data for compliance with specified temperature and pressure profiles throughout the operating cycle [see 9.3 c)].

NOTE Data printed can consist of digital records, analogue curves or both.

4.3.7.1.3 The recorder may 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.

4.3.7.1.4 If used, the data link shall allow the external system to generate records, which are compliant to all applicable specifications of 4.3.7.

4.3.7.1.5 The recorder shall produce a record, which shall be readable as defined in 4.3.7.1.9 when stored in specified conditions for a period of not less than 10 years.

4.3.7.1.6 A record can be a print-out or projected from a digitally stored record file. If a system is used that does not deliver paper copies for the release of product, attention shall be paid to the integrity of the original digital data provided for storage.

NOTE If the reports are not in a paper format, dedicated digital data presentation can support formal procedure for product release.

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

4.3.7.1.8 Recorders shall have a sampling interval of 2 s or lower for each channel.

4.3.7.1.9 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.

4.3.7.1.10 If times are marked, units shall be either in seconds, minutes or hours or multiples thereof. Time periods up to 5 min shall have an uncertainty of measurement of ± 2,5 % or less and for periods above 5 min of ± 1 % or less.

4.3.7.1.11 Means shall be provided to adjust the recorder by the use of an access device.

4.3.7.2 Recorders producing analogue records

4.3.7.2.1 Recorders producing analogue records shall have a chart speed of not less than 2 mm/min.

4.3.7.2.2 If two or more variables are recorded on the same chart, the printed scale markings on the chart shall be common for all the variables recorded and the major marked interval shall be marked sequentially for each of the variables recorded.

4.3.7.2.3 Recorders producing analogue records shall have a minimum scale width of 100 mm.

4.3.7.2.4 Temperature recorders producing analogue records shall:

— have a chart graduated in degrees Celsius;

— have a scale, which includes the range 0 °C to 100 °C;

— have maximum permissible errors of 1 % or less over the scale range 0 °C to 100 °C;

— be adjusted to ± 1 °C or less at the sterilization temperature.

4.3.7.2.5 Pressure recorders producing analogue records shall:

— have a chart graduated in bars or kilopascals;

— have a scale which includes the range 0 kPa (0 bar) up to the maximum process operating pressure;

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

— be adjusted to 1,0 kPa (0,01 bar) or better over the scale range.

4.3.7.3 Recorders producing digital records

4.3.7.3.1 Recorders producing digital records shall use alphanumeric characters and define data by text.

4.3.7.3.2 Recorders producing digital records shall have a paper width with a space for a minimum of 15 characters/line.

4.3.7.3.3 Temperature recorders producing digital records shall:

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

— have maximum permissible errors of 1 K or less over the range 20 °C to 100 °C.

4.3.7.3.4 Pressure recorders producing digital records shall:

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

— have maximum permissible errors of the record of 1,0 % or less over the scale range.

4.3.8 Indications and registrations

4.3.8.1 Sterilizer instrumentation shall make available to the operator at least the following visual information:

a) indication of the chamber pressure;

b) indication of the chamber temperature;

c) registration of the chamber temperature independent from the automatic controller;

d) registration of the chamber pressure independent from the automatic controller;

e) indication of the chamber wall temperature;

f) indication of the pressure or temperature of the formaldehyde vaporizer (for indication of the vaporization ability);

g) indication of the jacket pressure if the sterilizer is fitted with a pressurized jacket;

h) indication of steam supply pressure if dedicated steam generator is used;

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

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

k) indication of the operating cycle selected;

l) indication of sterilizer “in progress”;

m) indication of the operating cycle stage;

n) indication of “cycle complete”;

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

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

q) cycle counter.

NOTE 1 Items c), d) and q) can be incorporated into a single recording system.

NOTE 2 Items a), b), e), f), g) and h) can be incorporated into a system whereby the user can select the display of any measurement.

NOTE 3 Item m) cycle stage indication can incorporate items i), j), l), n) and p).

4.3.8.2 In addition, instrumentation at double-ended sterilizers shall provide the following visual information at the unloading side:

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

5.1.2 The sterilizer shall operate with pre-set programmes permanently stored in the automatic controller. Any change of the pre-set programme or its parameters shall require the use of an access device.

NOTE Automatic loading and unloading can be initiated without the use of an access device.

5.1.3 The variables and parameters programmed into the automatic controller and the tolerable limits that will still enable the performance requirements of Clause 6 to be met shall be specified. See also 9.3c).

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.

NOTE 1 Guidance is given in EN 60204–1.

NOTE 2 Verification can be achieved by assessing compliance with EN 60204–1.

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 Normally the temperature and humidity in the vicinity of the control system are below 50 °C and 85 % relative humidity respectively.

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

NOTE These can be located within the enclosure of the controller.

5.1.7 The reference measurement point shall be selected in such a way that throughout the holding time the temperature at this point correlates with the temperature in the usable space.

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 ISO 13849-2, EN 61508–3, EN 62304 and EN 62061 can support activities to be performed.

5.3 Operating cycle and automatic control

5.3.1 Leak testing shall be performed either during the first vacuum phase or during the complete holding time.

For cycle control, if the test is carried out during the first vacuum phase, a pressure stabilising time not exceeding 15 min may precede the test period.

The pressure change measured shall be ≤ 50 Pa (0,5 mbar) per minute when tested over a period of 10 min.

A pressure rise due to media injection during the holding time shall not be considered as a leak for the evaluation of the leak rate.

There shall be a visual and/or audible indication if the test fails. The operating cycle shall be interrupted automatically by aeration and, in case the sterilant has already been injected, the desorption operating stage shall be started immediately.

5.3.2 The cycle variables identified during process development as critical to the sterilization cycle shall be reproducible within the limits identified in 5.1.3. This shall be demonstrated by the tests specified in Table B.1.

5.3.3 Means shall be provided to ensure that the specified amount of microbicidal solution has been supplied to the vaporizer and has been vaporized.

5.3.4 The automatic controller shall ensure that all chemical/physical conditions necessary for the efficacy and reproducibility of the sterilization cycle are achieved throughout the specific periods.

NOTE Ab-/adsorption of formaldehyde to the load and formation of paraformaldehyde can reduce the concentration of gaseous formaldehyde in the chamber during the process.

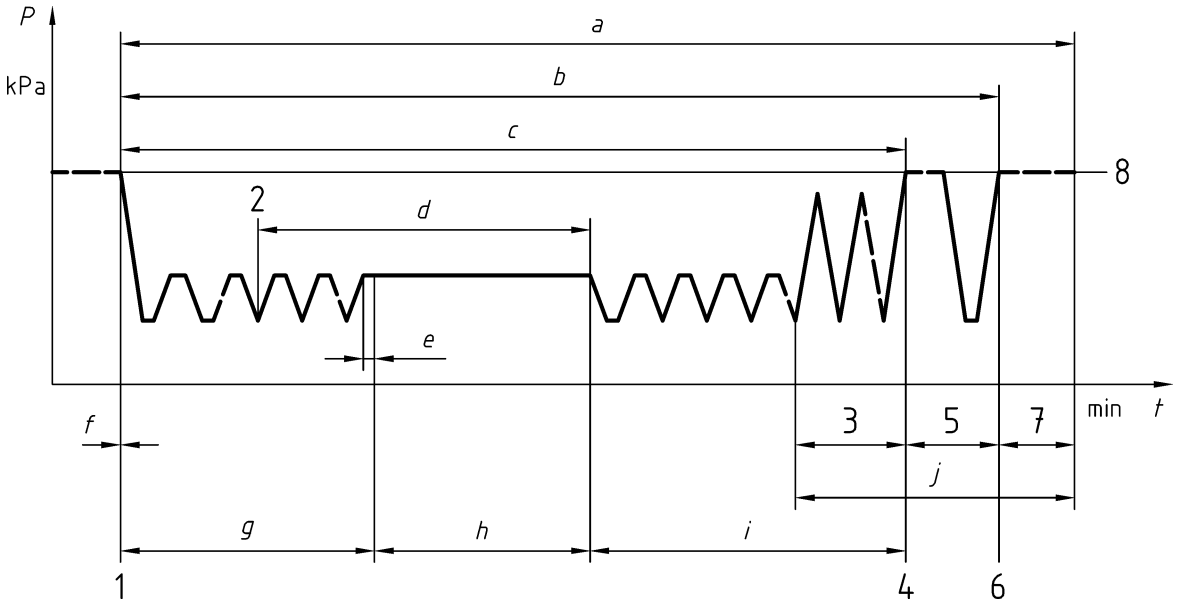
5.3.5 The sterilization cycle shall include a desorption phase (see 6.2 and EN 61010–2–040:2005, Clause 13).

5.3.6 The stage advance system of the automatic controller shall ensure that during an operating cycle, switching from one operating stage to another will only be possible when the values required for advance have been attained.

5.3.7 An automatic post cycle flushing shall run or be repeated until the unloading door is opened for removal of the sterilizer load. This flushing-sequence shall be continuous or otherwise ensure that when opening the unloading door, the formaldehyde concentration in the chamber and load does not constitute a hazard to human beings or environment.

NOTE 1 Desorption of condensate residuals from the sterilized load can continue when the sterilized load is left in the sterilizer chamber.

NOTE 2 In order to maintain this ability, a separate maintenance operating cycle can be used to remove accumulated formaldehyde residuals from the sterilizer chamber and piping.



Key

1 cycle start
2 start sterilant injection
3 flushing within cycle
4 cycle complete indication
5 post-cycle flushing
6 cycle complete indication at delayed door opening/unloading
7 removal of sterile goods (if necessary aeration outside the sterilizer)
8 ambient pressure

a sterilization process
b operating cycle
c sterilization cycle
d exposure time
e equilibration time
f pre-heating
g air removal and conditioning
h holding time
i desorption
j aeration

Figure 4 — Example of a LTSF sterilization process demonstrating relations of process parts

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.

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 power failure the requirements in 5.5.2 to 5.5.8 shall apply after restoration of the power supply.

5.5.2 If the cycle variables values are outside the limits specified by the manufacturer (see 5.3.2) or a failure of a service occurs sufficient to prevent the attainment of these variables, 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 operating cycle stage at which the fault has occurred.

5.5.3 After a fault has been indicated the automatic controller shall either:

a) permit automatic completion of all remaining stages of the operating cycle, at which there shall be no indication of cycle complete, or;

b) permit automatic progress to the sterilant removal stage, followed by automatic progression through the remaining stages of the operating cycle, with no indication of cycle complete, or;

c) allow manual progression through the cycle to a safe condition with no indication of cycle complete.

NOTE Additional guidance regarding safety and faults can be found in EN 61010–2–040.

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 formaldehyde injection has been started, the controller shall ensure that the sterilizer chamber cannot be opened until the formaldehyde has been sufficiently removed from the chamber (see also EN 61010–2–040:2005, 7.102, and 13.1 including following subclauses).

5.5.6 If a fault occurs prior to or during the sterilization phase, the load is considered non-sterile and the control shall ensure that for double-ended sterilizers the unloading door cannot be opened.

5.5.7 If the sterilizer is fitted with a printer, the indication of a fault shall also be distinguishable from the normal printing e.g. by inverse printing.

5.5.8 After completion of a faulty cycle, access to the sterilizer load shall require the use of an access device.

5.5.9 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 Physical testing

6.1.1.1 Pre-heating

When tested as described in A.3.2.1, the temperature of the heated internal surfaces of the sterilizer chamber shall comply with the specifications given by the manufacturer.

6.1.1.2 Sterilization temperature band

The sterilization temperature band shall not exceed 4 K.

6.1.1.3 Temperature profile

During testing according to Annex A, the following temperatures shall be used for the evaluation of the temperature profile:

— the temperature measured at the reference measurement point;

— the theoretical sterilant temperature as calculated from the corresponding prevailing chamber pressure;

— the temperatures in positions as specified in A.3.2.2 and A.3.2.3.

6.1.1.4 Temperature profile requirements

Throughout the sterilization cycle the temperature at the reference measurement point shall not exceed the upper limit of the sterilization temperature band.

During the cycle, until any aeration sequence is started, the theoretical sterilizing temperature shall not exceed the upper limit of the sterilization temperature band.

The equilibration time shall not exceed 60 s before entering the holding time.

During the holding time the temperatures as specified in 6.1.1.3 shall:

— be within the sterilization temperature band;

— not differ from one another by more than 2 K.

Compliance shall be tested according to A.3.2.2 and A.3.2.3.

6.1.1.5 Pressure profile

The pressure profile is evaluated by measurement of the sterilization cycle pressure. The measurement shall include limiting values to establish the profile of all sequences as well as data sufficient to evaluate tolerances and the rate of pressure change in applicable parts of the sterilization cycle. The result shall be compared with corresponding specifications stated by the manufacturer [see 9.3 c)].

Pressure measurement for the evaluation of the pressure profile shall be barometrically compensated.

6.1.1.6 Pressure profile requirements

Throughout the sterilization cycle the pressure profile and limiting values specified for the pressure profile shall be attained.

The maximum rate of pressure change measured shall not exceed 1000 kPa/min (10 bar/min) when measured over a period of 3 s.

NOTE 1 Pressure changes exceeding 1000 kPa/min (10 bar/min) can damage the packaging systems.

During the holding time the pressure profile shall be kept within the tolerances specified.

NOTE 2 There is a close relation between the pressure profile and the temperature profile in the sterilizer chamber throughout the holding time.

Compliance shall be tested according to A.3.4.1 and A.3.4.2.

6.1.1.7 Sterilant

The physical and chemical control parameters for the supply of sterilant to the process (e.g. temperature, partial pressure, concentration), as verified during process development and stated in the manual [see also 9.3 c)], shall be achieved reproducibly within the pre-set values and tolerances.

6.1.2 Lethality (Microbiological efficacy)

When tested in accordance with A.3.3, the sterilization cycle shall ensure that exposed biological indicators are no longer viable when subjected to the culture conditions as specified for these indicators. Untreated biological indicators shall be viable when cultured in the same manner.

6.2 Desorption efficacy

The removal of formaldehyde from the sterilizer chamber and load at the desorption stage of the operating cycle shall ensure that the maximum stipulated concentration of formaldehyde in the environment or in/on processed items will not be exceeded when the load is removed from the sterilizer.

NOTE 1 In many countries national regulations exist limiting formaldehyde concentration in air. These regulations restrict emission of formaldehyde to air from LTSF sterilizers.

NOTE 2 The complete removal of formaldehyde residuals from the sterilizer chamber and piping can in addition to the normal sterilization cycle require a separate maintenance cycle or procedure to be used periodically.

When tested in accordance with A.3.5, the desorption stage of the sterilization cycle shall be able to reduce the value of formaldehyde residues in/on processed items as follows:

— the mean value calculated for test pieces of the same test load shall not exceed 200 µg;

— the value for any single test piece shall not exceed 400 µg.

NOTE 3 Test results from practice have shown a rather large variance of the formaldehyde residue values up to 30 % (standard deviation). It is assumed that this is caused by stochastic distribution of condensate accumulations inside the chamber and at the load (test pieces) during the process.

These values are valid for indicators with a diameter of 70 mm. For indicator diameters differing from 70 mm the figures shall be compensated proportionally to the change in surface area.

6.3 Drying

The sterilization cycle shall ensure that no part of the packaging systems in the sterilized load are wet when unloading, and that any remaining water droplets of the inner side of wrappings shall be evaporated within 5 min.

Compliance shall be tested according to A.3.6.

7 Sound power and vibration

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, A-weighted sound power and emission sound pressure levels shall be determined and specified for each type of sterilizer. For testing and calculation EN ISO 3746:2010 shall apply.

NOTE 1 Without the use of protective earpieces, a sound power level of 80 dB(A), an emission sound pressure level at workstations of 70 dB(A), and a single event time integrated sound pressure level of 135 dB(A) are regarded as the threshold at which a hazard can be caused. A lower threshold level can apply in some noise sensitive environments e.g. a clinical procedure room.

During the test, any part necessary for the correct operation of the equipment and supplied by the manufacturer as an integral part of the equipment, e.g. a pump is operated as in normal use. The combination of load and other operating conditions e.g. pressure, flow, temperature shall be those that create the maximum sound pressure level.

NOTE 2 For test and calculation other methods of demonstrated equivalence can be used.

7.3 If specified, the emission sound pressure level shall apply for the operator's position in front of the sterilizer at a distance of 1 m and a height of 1,6 m. Where the A-weighted emission sound pressure level at workstation of 70 dB (A) is not exceeded at least this fact shall be indicated in the equipment specification.

If not evaluated different from dedicated tests, the standard deviation for the sound power and emission sound pressure levels shall be stated to be +5 dB (see EN ISO 3746:2010, Table D.1).

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

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

8 Packaging, marking and labelling

8.1 The sterilizer package shall be designed to protect the sterilizer and preserve 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 A Council Directive on the approximation of the laws of the member states concerning pressure equipment was released on 29 May 1997 (97/23/EC) [3] and corresponding European Standards EN 13445 (series) and EN 14222, are available.

These standards establish marking requirements for pressure vessels.

8.4 Markings and labels shall be permanently and legibly marked. For specific markings, EN ISO 15223-1 applies.

8.5 Markings regarding safety and environmental aspects of the equipment are specified in EN 61010-2-040:2005, 5.2.

8.6 Markings shall include at least:

a) name/company and address of the manufacturer. The address shall include: street/road, number/house/floor, postal code, city, state/region and country;

b) name and address of authorized representative within the European Community 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 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 devices;

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 the microbicidal solution and sterilant required for the sterilization, including composition, safety data sheet and storage requirements;

d) details of maximum consumption of microbicidal solution per sterilization cycle;

e) the total heat in watts transmitted to the surrounding air when the sterilizer is operated in an ambient temperature of (23 ± 2) °C in still air;

NOTE 2 The heat transmitted by sterilized load can affect the design of the ventilation system.

f) dimensions of the usable space and the loading capacity of the sterilizer;

g) the A-weighted sound power and sound pressure levels generated by the sterilizer, as specified by Clause 7;

h) the sound power levels for any additional device, delivered with the sterilizer but separate from it, and which is necessary for its operation;

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

j) declaration of compliance with the EMC requirements in 4.2.2.3;

k) notification that national legislation about limitations on formaldehyde concentration in air at the working place may exist (see also F.3);

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

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

n) further details of equipment installation for safety as required by EN 61010–2–040:2005, 5.4.3, 5.4.3.101 and 7.1.101;

o) ambient lighting and appropriate lighting of maintenance area(s)

NOTE 3 Guidance for lighting is provided in EN ISO 12100:2010, 4.8.6 and EN 1837:1999+A1:2009, Clauses 4 and 5.

p) instructions for disposal of the sterilizer packaging.

9.3 The user instruction shall accompany the sterilizer delivery and be provided within the sterilizer packing. It shall include at least:

a) identification of sterilizer manufacturer;

b) the CE-mark including, if applicable, the notified body identification number

c) general description of the field of application with available sterilization cycles, including values and tolerances for the cycle parameters for which efficacy and safety has been established (see also 5.1.3 and Annex B);

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

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

NOTE 1 This can include instructions for disposal.

f) dimensions of the sterilizer chamber;

g) description of controls as well as indicating, operating and recording devices;

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

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

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

NOTE 2 The frequency and extent of validation, and requalification activities are not a part of the sterilizer documentation. National guidance can exist on this topic.

k) brief description of safety devices;

l) further details of equipment operation for safety as required by EN 61010–2–040:2005, 5.4.4;

m) instructions for loading;

n) instructions on the protective measures to be taken by the users, including, where appropriate, the personal protective equipment to be provided;

o) warnings and precautions about the residual risks;

p) date of issue or date of latest revision of the instructions;

9.4 Brief operating instructions shall accompany the delivery of the sterilizer.

9.5 Before the installation qualification, the following information shall be available to the user:

a) maintenance manual including at least:

1) Maintenance activities including maintenance intervals;

2) safety device checks and settings;

3) wiring and piping diagrams;

4) guidance for service and spare parts;

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

b) manufacturer's declaration on conformity with this standard;

c) details of required data and qualities of services and sterilant [see 9.2 c)];

d) the location of the reference measurement point;

e) reference to Annex E and Annex D of this standard for informative data regarding limitations of formaldehyde residues on medical devices and methods for their determination respectively;

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

g) further details of maintenance of safety equipment as required by EN 61010–2–040:2005, 5.4.5;

h) instructions for disposal of the sterilizer.

9.6 An attachment for documents intended for routine use shall be provided.

9.7 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 9.4).

9.8 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 authorized 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

10.1General

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

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

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

10.2Electricity

Electrical supply system, configuration, voltage, including minimum and maximum values, and connected power shall comply with the specifications provided for the sterilizer. A stationary connection shall be provided [see 9.2 b) and 10.1].

10.3Sterilant

10.3.1 Vaporizing a microbicidal solution, prepared in a ratio specified for the process, shall generate the sterilant.

10.3.2 The composition and concentration of the microbicidal solution shall correspond to the specifications provided for the process.

10.3.3 The microbicidal solution to be used shall be stabilised (e. g. by methanol) to reduce polymerisation.

10.3.4 The microbicidal solution containers intended for use in the sterilizer shall correspond to the specifications provided for the sterilizer.

10.3.5 If the sterilizer requires other supplies than the microbicidal solution, it shall be ensured that they are non-interchangeable.

10.3.6 Storage requirements and expiry date of the microbicidal solution shall be stated on containers intended for use in the sterilizer.

10.4Steam

10.4.1 Steam generated by a dedicated steam supply or steam from an external supply may be used.

10.4.2 The quality of steam required for the process shall be according to specifications [see 9.2 b) and 10.1].

NOTE EN 285 can be used as a guidance document.

10.5Water

10.5.1Water used for sterilizer operation

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

NOTE 1 Keeping the temperature of water as low as possible can be important as higher water temperatures can reduce the capacity of the vacuum system.

NOTE 2 Water of a hardness value between 0,7 mmol/l and 2,0 mmol/l, are generally accepted values used for the design of the sterilizer. Hardness values outside these limits can cause scaling and corrosion problems.

NOTE 3 For quality of potable water, see Directive 98/83/EC [4].

NOTE 4 National regulations can require a backflow protection in the supply line.

10.5.2Feed water

The requirements for water intended for steam production within the sterilizer or for a dedicated steam supply shall be specified [see 9.2 b) and 10.1].

NOTE Water containing higher concentrations of contaminants can impair the sterilization cycle or harm the sterilizer or sterilized load. EN 285 provides additional guidance.

10.6Compressed air

If compressed air is required, it shall:

— be filtered to 25 µm;

— free of liquid water and oil droplets greater than 2 µm;

— be supplied at a pressure specified for the sterilizer [see 9.2 b) and 10.1].

10.7Drainage and discharges

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

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

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

10.8Ventilation and environment

The sterilizer shall be designed to operate at a temperature and relative humidity of 35 °C and 85 % respectively.

NOTE This can require the provision of a ventilation system designed and constructed to remove the heat transmitted from the sterilizer and from the sterilizer load when unloading.

Installation site ventilation facilities shall be installed as required by safety or environmental aspects in EN 61010-2-040:2005, 11.101 and 13.1 including following subclauses.

10.9Lighting

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

Annex A
(normative)

Test methods

A.1 General

The performance of the sterilizer shall be tested according to this annex. Additionally Table B.1 sets up requirements for the applicability and number of tests to be performed for each type of sterilizer. The tests described in this annex shall be performed with an empty sterilizer chamber, with small load or full load as specified for each test procedure in A.3 below. By combining the test loads for different test methods, the tests may be performed simultaneously.

NOTE 1 By performing tests simultaneously, as described by the following test methods, the total number of tests and test equipment disposals is reduced. As a result the burden on the environment can be reduced (see also Annex F).

NOTE 2 The reference test loads are specified to enable verification of conformity with the requirements in this standard. They can be used for type tests, production tests and operational qualification but not for performance qualification.

A.2 Test loads

A.2.1 Small load

A.2.1.1 General

The small load is selected to represent a normal loading situation for a LTSF sterilization cycle. The small load shall be composed of small load units, as defined in A.2.1.2, increasing in numbers as a result of increasing sterilizer chamber volume.

One small load unit shall be used per 10 l of usable space for chamber volumes up to 100 l.

For chamber volumes > 100 l one small load unit shall be added per 25 l of additional usable space, in addition to the initial 10 units required for the first 100 litres.

A.2.1.2 Small load unit

The small load unit shall consist of 3 process challenge devices as defined in C.6, double wrapped using paper wrapping as defined in C.8.

A.2.2 Full load

A.2.2.1 General

The full load is selected to represent a heavy loading situation for a LTSF sterilization cycle. It shall comprise at least 90 % in weight of the maximum load as specified for the sterilizer [see 9.2 f)].

It shall be composed of a number of full load units, as defined in A.2.2.2, amounting to at least 15 % in weight of the maximum load, plus a mixture of items similar to those used in the full load units and with similar material proportions.

NOTE The weight of the load support system is not included in the weight of the maximum load.

A.2.2.2 Full load unit

The full load unit shall consist of the following sets of items:

a) One hose made of polyvinylchloride (PVC) with a length of 1500 mm, with an inner diameter of 4 mm and an outer diameter of 6 mm. The item shall be double wrapped and have a total weight of (40 ± 5) g.

b) One hose made of polyvinylchloride (PVC) with a length of 1000 mm, with an inner diameter of 8 mm and an outer diameter of 12 mm and one screw made of stainless steel, M 8 x 60 (see e. g. EN ISO 4017), which is pushed into one end of the PVC hose. The complete item shall be double wrapped and have a total weight of (120 ± 10) g.

c) One rod made of polyamide (PA11 or PA12 according to EN ISO 1874-1) with a length of 80 mm and a diameter of 15 mm, and one screw made of stainless steel, M 8 x 60 (see e. g. EN ISO 4017). Both items shall be double wrapped together and have a total weight of (45 ± 5) g.

d) One tube made of stainless steel (e. g. X5CrNi18-10 [1.4301] according to EN 10027-2) with a length of 230 mm, with an inner diameter of 6 mm and an outer diameter of 8 mm. The item shall be double wrapped and have a total weight of (45 ± 5) g.

e) One process challenge device as defined in C.6, double wrapped.

For wrapping transparent plastic/paper compound wrapping as defined in C.8 shall be used. The total weight of the full load unit excluding load carrier facilities will be (250 ± 25) g.

NOTE 1 Two sets of items [type b) and c)] are used for the full load temperature profile and the pressure tests and are not sealed in advance.

NOTE 2 Disposal instructions for wrappings and, if applicable, for test items, are provided by its manufacturer.

A.3 Test procedures

A.3.1 Test equipment

The test equipment shall meet the requirements of Annex C.

A.3.2 Thermometric tests

A.3.2.1 Sterilizer chamber pre-heating test

A.3.2.1.1 The pre-heating test is used to demonstrate that inside surface temperatures of the sterilizer chamber (including the doors) will be held within a specified range providing validated physical conditions during normal sterilization.

A.3.2.1.2 Introduce at least 10 temperature sensors into the sterilizer chamber for sterilizers with a volume up to 1000 l and one additional temperature sensor per any additional 100 l, using the test connection as specified in 4.1.5.2. Distribute the sensors on representative inner chamber surfaces specified for the sterilizer [see 9.3 f)] check.

A.3.2.1.3 Carry out the measurements in an evacuated empty chamber.

A.3.2.1.4 Check for compliance with performance requirements in 6.1.1.1 after completion of the pre-heating time.

A.3.2.2 Small load temperature profile test

A.3.2.2.1 The small load temperature profile test is primarily used to demonstrate that temperatures versus pressure conditions within this load are such that sterilization is enabled. Secondly, the test demonstrates that temperatures do not exceed the upper limit of the sterilization temperature band throughout the complete sterilization cycle.

NOTE The test can be carried out as separate small load test, alternatively as an integrated part of a pressure profile, microbiological, drying or desorption test, as applicable.

A.3.2.2.2 Connect the pressure-recording instrument to the sterilizer chamber using the test connection described in 4.1.5.1.

A.3.2.2.3 Place the small load units as defined in A.2.1 into the usable space of the sterilizer chamber using the load support system of the sterilizer and considering loading instructions specified for the sterilizer [see 9.3 m)].

A.3.2.2.4 Place the number of temperature sensors as specified in Table B.1 inside the sterilizer chamber.

NOTE The test connection specified in 4.1.5.1 can be used.

A.3.2.2.5 Place one temperature sensor at the reference measurement point. Distribute the remaining temperature sensors evenly within the usable space occupied by the test load paying attention to identified and documented critical positions.

NOTE Critical positions can be identified during development.

A.3.2.2.6 Immediately start the sterilization cycle to be tested. After completion of the cycle, check that a visual display of cycle complete is obtained before unloading the sterilizer.

A.3.2.2.7 Examine the records for compliance with the performance requirements in 6.1.1.4.

A.3.2.3 Full load temperature profile test

A.3.2.3.1 The full load temperature profile test is primarily used to demonstrate that temperatures and pressure are within the process specification, thus enabling sterilization. Secondly, the test demonstrates that temperatures do not exceed the upper limit of the sterilization temperature band throughout the complete sterilization cycle.

NOTE The test can be carried out as separate full loads test, alternatively as an integrated part of pressure profile, microbiological or drying tests as applicable.

A.3.2.3.2 Connect the pressure-recording instrument to the sterilizer chamber using the test connection described in 4.1.5.1.

A.3.2.3.3 Place the full load units into the usable space of the sterilizer chamber. The load support system of the sterilizer shall be used, considering loading instructions specified for the sterilizer [see 9.3 m)].

A.3.2.3.4 Place the number of temperature sensors as specified in Table B.1 inside the sterilizer chamber.

NOTE The test connection specified in 4.1.5.1 can be used.

A.3.2.3.5 Place one temperature sensor at the reference measurement point.

Select one full load unit and insert two temperature sensors into the sets of items b) and c) of A.2.2.2 by piercing the wrappings. Use adhesive tape to fix the sensors in good thermal contact with the screws inside the wrappings and seal the sensor perforations of both wrappings. Seal the double wrappings and return the sets of items into the full load unit. Place this full load unit into the usable space of the sterilizer chamber at the location that was identified during the small load temperature profile test as the coldest spot of the load. Distribute the remaining temperature sensor(s) evenly within the usable space occupied by the test load.

A.3.2.3.6 Immediately start the sterilization cycle to be tested. After completion of the cycle check that a visual display of cycle complete is obtained before unloading the sterilizer.

A.3.2.3.7 Examine the records for compliance with the performance requirements in 6.1.1.4.

A.3.3 Microbiological test

A.3.3.1 LTSF-sterilization processes usually consist of air removal and conditioning (phase 1) followed by the holding time (phase 2). Both phases together contribute to microbial inactivation. Additionally, microbial inactivation continues during desorption. Therefore it is difficult to define and perform a reduced cycle, and consequently, a full cycle, using appropriate biological indicators.

A.3.3.2 The microbiological test is intended to show that when physical conditions during temperature and pressure profile tests have been demonstrated to fulfil the performance requirements of this standard, recovery of test organisms from the biological indicator placed in the test load cannot be obtained after the completion of a successful sterilization cycle.

NOTE The test can be carried out as a separate test, alternatively as an integrated part of temperature profile, pressure profile, drying or desorption tests, as applicable. However, when carried out simultaneously with a desorption test, the number of wrappings (PCD's) included in the dedicated test load are preferably equal to or greater than the total number of indicators used for both tests. Mutual influence of results can be avoided by packing the biological and desorption indicators separately.

A.3.3.3 The number of indicators to be used depends on the loading capacity of the usable space. The number of the indicators shall be such that the lethality effect achieved within the sterilization load can be evaluated. Biological systems as defined in C.7 shall be used and the minimum number of indicators needed is given in Table B.1.

A.3.3.4 Place each indicator excluding the positive control in process challenge devices (see C.6), which are double-wrapped and sealed using sterilization wraps according to EN 868–5.

A.3.3.5 Distribute the double-wrapped PCD's evenly within the usable sterilizer chamber space and document the distribution.

A.3.3.6 Immediately start the sterilization cycle to be tested. After completion of the cycle, check that a visual display of cycle complete is obtained before unloading the sterilizer.

A.3.3.7 Culture both the exposed and the untreated biological indicators in accordance with EN ISO 11138-1.

A.3.3.8 Check for compliance with 6.1.2.

A.3.4 Pressure profile tests

A.3.4.1 Small load pressure profile test

A.3.4.1.1 The small load pressure profile test is primarily used to demonstrate that the requirements for the sterilization cycle pressure profile, as specified in 6.1.1.5, are fulfilled under small load conditions. Secondly, the test demonstrates that the rate of pressure change during the sterilization cycle is kept within a range not damaging the load including the wrapping.

NOTE The test can be carried out as separate small load test, alternatively as an integrated part of temperature profile, microbiological, drying or desorption tests, as applicable.

A.3.4.1.2 Connect the pressure recording instrument to the sterilizer chamber.

NOTE The test connection specified in 4.1.5.1 can be used.

A.3.4.1.3 Place the small load units into the usable space of the sterilizer chamber using the load support system of the sterilizer and considering loading instructions specified for the sterilizer [see 9.3 m)].

A.3.4.1.4 Immediately start the sterilization cycle to be tested. After completion of the cycle check that a visual display of cycle complete is obtained before unloading the sterilizer.

A.3.4.1.5 Examine the records for compliance with the performance requirements in 6.1.1.6.

A.3.4.2 Full load pressure profile test

A.3.4.2.1 The full load pressure profile test is primarily used to demonstrate that the requirements for the sterilization cycle pressure profile, as specified in 6.1.1.5, are fulfilled under heavy load conditions. Secondly, the test demonstrates that the rate of pressure change during the sterilization cycle is kept within a range not damaging the load including the wrapping.

NOTE The test can be carried out as separate full load test, alternatively as an integrated part of temperature profile, microbiological or drying tests, as applicable.

A.3.4.2.2 Connect the pressure recording instrument to the sterilizer chamber

NOTE The test connection specified in 4.1.5.1 can be used.

A.3.4.2.3 Place the full load units (see A.2.2) into the usable space of the sterilizer chamber using the load support system of the sterilizer and considering loading instructions specified for the sterilizer [9.3 m)].

A.3.4.2.4 Immediately start the sterilization cycle to be tested. After completion of the cycle, check that a visual display of cycle complete is obtained before unloading the sterilizer.

A.3.4.2.5 Examine the records for compliance with the performance requirements in 6.1.1.6.

A.3.5 Desorption test

A.3.5.1 The desorption test is used to demonstrate that the sterilizer is able to reduce the level of formaldehyde on a medical device after sterilization to a level as specified in Annex E.

NOTE The desorption test can be carried out as separate small loads test, alternatively as an integrated part of small load temperature profile, pressure profile, drying or microbiological tests, as applicable. However, when carried out simultaneously with a microbiological test, the number of wrappings (PCD's) included in the dedicated test load are preferably equal to or greater than the total number of indicators used for both tests. Mutual influence of results can be avoided by packing the biological and desorption indicators separately.

A.3.5.2 The number of indicators to be used depends on the loading capacity of the usable space. The number of indicators shall be such that the desorption effect achieved within the sterilization load can be evaluated. The minimum number of indicators is given in Table B.1 and the indicator requirements are specified in C.5.

A.3.5.3 Place each indicator together with a PCD (see C.6) into a sealed sterilization pouch complying with standards as specified in C.8. Put them into a second wrapping to achieve a double-wrapped item and seal it. Keep a further indicator separate from the wrapped items. This indicator shall be used as a reference (blank) indicator and shall not be exposed to the sterilization cycle.

A.3.5.4 Distribute the double-wrapped indicators/PCD's evenly within the usable sterilizer chamber space and document the distribution.

A.3.5.5 Start the sterilization cycle to be tested immediately. After completion of the cycle check that a visual display of cycle complete is obtained before unloading the sterilizer.

A.3.5.6 Unpack the indicators and handle them according to the procedure described in D.1.

A.3.5.7 Determine the formaldehyde contents expressed in microgram (µg) for each processed indicator as well as for the reference (blank) indicator by using the methods described in D.2. Subtract the value (µg) representing the reference (blank) indicator from each value representing a processed indicator. Use the result to calculate the mean value for the processed indicators and check for compliance with 6.2.

A.3.6 Drying test

A.3.6.1 The drying test is used to demonstrate that the sterilization cycle is able to reduce remaining moisture to a level that does not cause wet packaging systems or results in other detrimental effects on processed items.

NOTE The drying tests can be carried out as an integrated part of the small and full load temperature or pressure profile tests.

A.3.6.2 Inspect the sterilized load and check for compliance with 6.3.

Annex B
(normative)

Sterilizer classification and testing

B.1 General

The series of tests listed in Table B.1 and specified in A.3 are tests intended for use with reference loads in demonstrating conformity with performance requirements specified in this standard.

B.2 Type of sterilizer

B.2.1 The “type of sterilizer” concept does establish when design alterations are of a character that requires tests to be repeated. If kept within the same sterilizer type, design variations in an individual sterilizer are not considered to influence the performance, and can therefore be exempted from repeated testing.

B.2.2 When demonstrating that a type of a LTSF sterilizer conforms with performance requirements specified in this standard, sterilizers classified as the same type shall have:

a) the same number of doors in the same configuration;

NOTE 1 Where it has been demonstrated that for a given size and type of door, there is no difference in the influence on the load between a door and a back plate, sterilizers with one or two of these doors do not constitute different types.

b) all service connections into the chamber in the same orientation;

NOTE 2 A mirror image of the original orientation does not constitute a new type.

c) the same control system with all sensors located in the same position and orientation;

NOTE 3 Where (a) change(s) in the control system does/do not affect the process sequence and the limiting values a renewed type test is not required.

NOTE 4 Where (a) change(s) in the control system does/do not affect the operation of the sterilization cycle, tests according to A.3.3 can be omitted in further type tests.

d) the same sterilization cycle including the same cycle parameters.

B.2.3 If all other design aspects remain the same, the following variations shall not constitute a new type:

a) height of the sterilizer chamber above the floor;

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

c) prolonging the holding time of the sterilization cycle;

NOTE 1 Using sterilant during the prolonged time period can affect the desorption ability of the sterilizer. In this case the desorption test described in A.3.5 is repeated.

d) prolonging the desorption stage;

e) any change of the design or provenance of equipment, providing there is available documented evidence to show there is no adverse effect on the performance of the sterilizer which can effect compliance with this standard.

NOTE 2 For documentation of design changes see EN ISO 13485:2012, 7.3.7.

B.3 Testing

B.3.1 General

Before taking the sterilizer into use testing required to substantiate its compliance with the performance requirements in this standard shall be carried out. A successful outcome of all tests given in Table B.1 demonstrate this compliance.

A number of the tests specified in Table B.1 can be complementary to validation and requalification.

If during the tests adjustment(s) is (are) made to the sterilizer during a test sequence such that a new sterilizer type as defined in B.2 is created, the sequence of tests shall be repeated.

Before carrying out any of the tests the accuracy and adjustment of temperature and pressure measuring devices shall be checked, and that they comply with the requirements of this standard.

NOTE Environmental aspects can be considered during testing by planning and performing the tests in a logical succession. Therefore, the risk for unnecessary repetitions of tests due to the need for technical alterations of the sterilizer in a late stage of the test succession can be minimized. By experience physical testing has shown to cause most adjustments. A logical succession of the tests in Annex A can be as follows:

1) preheating test;

2) small load pressure profile test;

3) small load temperature profile test including drying test;

4) full load pressure profile test;

5) full load temperature profile test including drying test;

6) microbiological test;

7) desorption test.

B.3.2 Type test

The type test is used to demonstrate that the operational specifications of each sterilizer type are fulfilled before it is placed on the market. The series of tests described in A.3 are suitable as type tests with respect to the requirements of this standard, when performed as specified in Table B.1 for each sterilizer type.

B.3.3 Production test

The production test is used to demonstrate compliance of each sterilizer with its type test performance. The series of tests listed in Table B.1 and specified in A.3 are reference tests recommended for use in demonstrating conformity with the performance requirements specified in this standard.

B.3.4 Installation qualification (IQ)

NOTE Requirements and guidance for IQ are given in EN ISO 25424 and are not a normative part of this standard.

For sterilizers submitted to IQ which are covered by this standard it should be confirmed that:

a) the marking and labelling specified in Clause 8 have been provided;

b) the documentation specified in Clause 9 have been provided;

c) safety systems and devices are in compliance with 4.2.2.1;

d) the services are within the range specified for the sterilizer [see 9.2 b), c) and Clause 10];

e) there are no leaks or unintended effluent or emissions;

f) it has been checked that there is no evidence of electromagnetic interference to or from adjacent equipment (see 4.2.2.3);

g) the available sterilization cycles correspond to the users specifications [see 9.3 c)].

B.3.5 Operational qualification (OQ)

NOTE Requirements and guidance for OQ are given in EN ISO 25424 and are not a normative part of this standard.

For sterilizers submitted to OQ which are covered by this standard it is recommended to carry out the series of tests described in A.3 as specified in Table B.1.

Table B.1 — Summary of test programme

Usable space in litres	**Minimum number of indicators including positive control/ reference (blank) indicator**		**Minimum number of temperature measuring points**	**Number of tests**									
				type test					**production test and/or OQ**				
	Small load	Full load		m[c]	t[c]	p[c]	de	dr	m[a]	t[b]	p[a]	de[a]	dr[a]
< 60	7 (m) + 5 (de)	one per full load unit (m)	4	3	3	3	3	3	1	1	1	1	1
60 to 100	11 (m) + 7 (de)		6	3	3	3	3	3	1	1	1	1	1
> 100	one additional indicator per each additional 100 l (m and de)		two additional temperature measuring points per each additional 100 l	3	3	3	3	3	1	1	1	1	1

m = microbiological test

t = thermometric test

p = pressure profile test

de = desorption test (small load only)

dr = drying test

[a] For sterilizers from serial production not relevant as production test

[b] For sterilizers from serial production this test is relevant either as a production or an OQ test

[c] These tests shall be carried out for both small and full loads

Annex C
(normative)

Test equipment

C.1 Pressure instrumentation

C.1.1 Test pressure instruments shall be used to check pressure indicating and recording instruments.

A barometrically compensated system shall be used.

C.1.2 The scale range of the test pressure instrument shall include at least the scale range of the instrument to be tested. The maximum permissible errors of the test pressure instrument shall not exceed 0,5 times the maximum permissible errors of the instrument to be tested.

C.1.3 The test pressure instrument shall have a valid test certificate.

C.1.4 Calibration of the test pressure instrument shall be carried out using a working or reference standard, which is traceable to the national standard or a primary standard.

C.1.5 The test pressure instrument shall be calibrated in accordance with its user instructions.

C.2 Temperature sensors

C.2.1 Temperature sensors shall be either platinum resistance and comply with Class A of EN 60751 or thermocouple and comply with one of the types of Tolerance Class 1 of EN 60584–2.

C.2.2 The major diameter of the temperature sensors used within the sterilizer chamber shall not exceed 1,0 mm when measured over the secondary insulation of the connecting wires.

C.2.3 The conditions to which temperature sensors are exposed, e.g. pressure, sterilant, steam, or vacuum shall not affect its performance characteristics.

C.2.4 Calibration of the temperature sensors shall be carried out using a working or reference standard, which is traceable to the national standard or a primary standard.

C.3 Temperature recording instrument

C.3.1 The recording instrument shall record the temperature from at least the number of temperature sensors as specified in Table B.1. The channels can be multiplexed or independent of each other. The sampling rate for each channel shall be 2 s or less.

C.3.2 The scale range for analogue temperature recording instruments shall include 0 °C to 100 °C. The minor mark interval shall not exceed 1 K and the chart speed shall be not less than 10 mm/min. The length of the scale shall be sufficient to provide a resolution not more than 0,5 K.

NOTE A zoom function, i. e. a scale range reduction, can be used to attain the above specifications.

C.3.3 Digital temperature recording instruments shall register and record in increments of not more than 0,1 K and the scale range shall include 0 °C to 100 °C.

C.3.4 The maximum permissible errors between 10 °C to 100 °C shall not exceed 0,25 K when tested in an ambient temperature of (20 ± 3) °C.

After adjustment the temperature measured by all temperature sensors shall not differ by more than 0,2 K when immersed in a temperature source within the temperature band. The temperature indication of the source shall have an uncertainty of measurement less than ± 0,1 K at the temperature measured.

C.3.5 Calibration shall be carried out using a working or reference standard, which is traceable to the national standard or a primary standard.

C.3.6 The temperature recording instrument shall have a valid test certificate.

C.3.7 The temperature recording instrument shall be calibrated in accordance with its user instructions and calibration shall include a temperature which is within the sterilization temperature band.

C.4 Pressure recording instrument

C.4.1 The pressure recording instrument may be integrated into the temperature recording instrument as an additional channel calibrated for pressure. The sampling rate for each channel shall be 1 s or less. All data sampled shall be used for the interpretation of the results.

C.4.2 The scale range for analogue pressure recording instruments shall include 0 kPa to 100 kPa absolute (0 bar to 1 bar). The minor mark interval shall not exceed 2 kPa (0,02 bar) and the chart speed shall be not less than 10 mm/min. The length of the scale shall be sufficient to provide a resolution not less than 1 kPa (0,01 bar).

NOTE A zoom function, i. e. a scale range reduction, can be used to attain the above specifications.

C.4.3 Digital pressure recording instruments shall register and record in increments of not more than 0,1 kPa (0,001 bar) and the scale range shall include 0 bar to 1 bar absolute (0 kPa to 100 kPa).

C.4.4 The total limit of error between 4 kPa and 100 kPa absolute (0,04 bar to 1 bar) for the indicator and measuring system shall not exceed 0,3 kPa (3 mbar) when measured in an ambient temperature of (20 ± 3) °C.

C.4.5 The natural frequency of the sensor and connected tubing shall be not less than 10 Hz and the time constant (0 % to 63 %) for rising pressure not greater than 0,04 s.

C.4.6 The pressure recording instrument shall have a valid test certificate.

C.4.7 Calibration shall be carried out using a working or reference standard, which is traceable to the national standard or a primary standard.

C.4.8 The pressure-recording instrument, when connected to a pressure sensitive element, shall be calibrated in accordance with its user instructions, and calibration shall include a pressure within the sterilization pressure band. The uncertainty of measurement at the sterilization pressure shall be less than ± 0,2 kPa (0,002 bar).

C.5 Desorption indicator

Standardized filter paper according to the specification in Table C.1 with a diameter of at least 70 mm shall be used.

NOTE For environmental guidance see Annex F.

Table C.1 — Specification for filter paper used for desorption indicators

Characteristic	Reference Standard	Unit	Value
Basis weight	see EN ISO 536	g/m^2	90 ± 3
Thickness	see EN ISO 534	mm	0,2 ± 0,04
Density	-	kg/m^3	450 (nominal value) [a]
Filtration speed (initial)		s	11 ± 2
Capillary rise (Klemm)	see ISO 8787	mm/10min	110
Dry tensile index MD/CD	see ISO 3781	Nm/g	25/14
Burst index	see EN ISO 2758	$kPam^2/g$	1,0
Ash content	see ISO 1762	%	< 0,01
[a] Quotient of basis weight value divided with thickness value.			

C.6 Process challenge device (PCD)

The process challenge device (PCD) shall be non-metallic, be designed in such a manner that the sterilant is prevented from penetrating through the walls into the device and comply with EN 867–5.

C.7 Biological indicators and systems

Biological indicators and systems shall comply with EN ISO 11138-5.

NOTE 1 An F_{BIO}-value of (33 ± 3) min at 60 °C for BI is considered adequate to demonstrate overkill using a full process. The minimum value is based upon the requirements in EN ISO 11138-5.

NOTE 2 Other indicator systems (e.g. self-contained biological indicators) complying with EN ISO 11138-5 can be used. If such a system includes a PCD EN 867–5 also applies.

C.8 Wrappings

Sterilization wrappings shall comply with EN 868–5.

Annex D
(normative)

Determination of formaldehyde residuals in a filter indicator

D.1 Procedure for sample preparation

After cycle complete is indicated either put the processed filter indicator within 5 min into the extraction reagent as described in D.2.2, or wrap it tightly into aluminium foil for extraction within 24 h.

D.2 Analysis of formaldehyde contents in filter indicator

D.2.1 Equipment

D.2.1.1 **Chromotropic acid reagent**: Dissolve 1 g chromotropic acid soda salt ($C_{10}H_6Na_2O_8S_2$ x 2 H_2O) in 100 ml distilled water. Add 450 ml 12,4 mol/l sulphuric acid (H_2SO_4). Store the solution in a dark place. The solution is durable for 8 h.

D.2.1.2 **Spectrophotometer** at a wavelength of 560 nm.

D.2.1.3 0,2 mol/l **NaOH**.

D.2.1.4 **Erlenmeyer flasks** (250 ml) with glass stopper.

D.2.1.5 **Water bath.**

D.2.1.6 **Formaldehyde solution** with a well-known concentration between 34 % and 38 % (used for calibration).

NOTE 1 Regulations and environmental effects of the disposal of used chemicals and indicators are subjects to be investigated and planned prior to use.

NOTE 2 Attention is drawn to necessary precautionary measures when handling chemicals that can be dangerous to persons or environment.

D.2.2 Extraction and evaluation procedure for processed indicators

D.2.2.1 Extract the processed filter indicators separately with 50,0 ml 0,2 mol/l NaOH at room temperature for at least 8 h. Use 250 ml Erlenmeyer flasks which are closed by glass stoppers.

D.2.2.2 Add 1,0 ml of the above-mentioned NaOH extract and 10,0 ml of the chromotropic acid reagent to small glass flasks which are closed by glass stoppers. Heat the flasks in a water bath at 100 °C which is protected from light for 45 min.

D.2.2.3 Cool the glass flasks in cold water by means of the water bath and then measure the absorption of the dilution at a wavelength of 560 nm by using the spectrophotometer. Calculate the formaldehyde residues for each indicator in microgram (µg) formaldehyde by means of the diagram established by calibration as described in D.2.4.

D.2.3 Extraction and evaluation procedure for the reference (blank) indicator

D.2.3.1 The blank extraction is used for a filter indicator that has not been exposed to formaldehyde sterilization, and is used to establish a comparative residue value for a blank (non-processed) indicator. The extraction and evaluation of the reference (blank) indicator shall be carried out as described in D.2.2.

D.2.3.2 At the final evaluation of the desorption test (see A.3.5), the quantity of formaldehyde in the reference (blank) indicator shall be subtracted from the quantity of each processed indicator.

D.2.4 Calibration

D.2.4.1 Principle

The calibration procedure is used to establish a diagram for transforming the spectrophotometer readings directly into a quantity of formaldehyde expressed as microgram (µg) per indicator.

A formaldehyde solution with a known concentration of formaldehyde forms the basis of the calibration. This solution is diluted into several ratios to form samples with less concentration, which is determined very precisely. After performing a calibration procedure as described in D.2.4.2, a diagram including the parameter microgram (µg) formaldehyde per indicator as a function of the absorption value received as spectrophotometer reading is established. This diagram is used to determine the formaldehyde quantity which can be directly read off or calculated by means of the inclined line of the graph.

D.2.4.2 Procedure

D.2.4.2.1 Prepare a series of 6 samples with different formaldehyde concentrations as follows:

a) Dilute 1,0 ml of the concentrated formaldehyde solution into 1 000 ml.

NOTE A formaldehyde solution with a concentration of *n* % formaldehyde contains *n*/100 kg/l = 10 x *n* g/l = 10 x *n* mg/ml. The concentrated formaldehyde solution contains 34 % to 38 % formaldehyde and a solution diluted to 1:1 000 will contain 340 µg/ml to 380 µg/ml, i. e. a solution of 36,4 % contains 364 µg/ml.

b) Use the diluted solution and dilute further samples in concentration ratios of 1:2, 1:4, 1:8, 1:16 to obtain values with a sufficient measuring range.

c) Take 1,0 ml from each sample of the dilution in a) and b) and add 49,0 ml 0,2 M NaOH.

d) Prepare a further sample by adding 1,0 ml distilled water (representing the concentration 0 µg/ml) in 49,0 ml 0,2 mol/l NaOH.

D.2.4.2.2 To further increase the measuring safety repeat the steps a) to d) to gain two parallel series of equal dilutions.

D.2.4.2.3 Add 1,0 ml from each of the above-mentioned sample and 10,0 ml of the chromotropic acid reagent into small glass flasks which are closed by glass stoppers. Heat these flasks in a water bath at 100 °C protected from light for 45 min and continue by cooling them by means of the water bath.

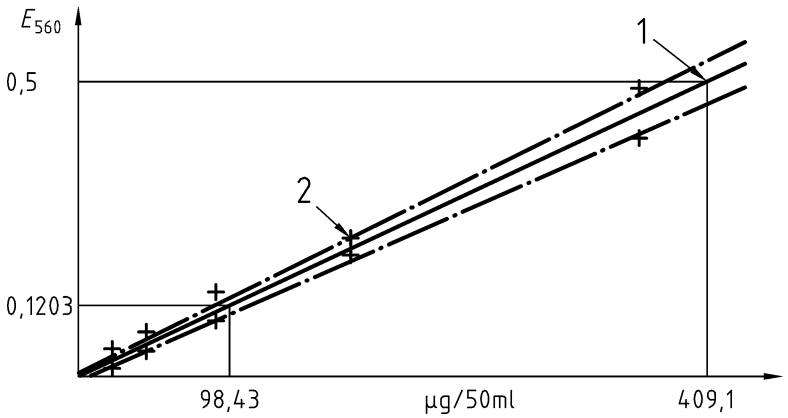
Two sets of calibrated samples designed for spectrophotometer analysis that are representing 0; *n* x 10; *n* x 10/2; *n* x 10/4; *n* x 10/8 and *n* x 10/16 µg formaldehyde dissolved in 50,0 ml solution are hereby established.

D.2.4.2.4 Establish a diagram with one axis representing spectrometer readings and the other axis representing microgram formaldehyde per 50 ml of solution.

D.2.4.2.5 Measure the absorption of each of the 6 samples of the 2 sets at a wavelength of 560 nm using the spectrophotometer. Out of the values measured and their known relationship to the formaldehyde contents per 50 ml of solution, insert two straight lines into the diagram according to the minimal square method (linear regression).

NOTE The minimal square method or linear regression is an established mathematical method used to minimize the sum of digression between the inserted (6) values and the straight line binding them together.

D.2.4.2.6 Finally calculate the arithmetic mean straight line out of the two lines inserted. This line now enables the total formaldehyde contents (µg) in 50 ml of 0,2 M NAOH, to be read off directly as a function of the spectrophotometer absorption value at 560 nm.



Key

1 slope 409,1/0,5 = 818,2µg/E_{560}

2 sample value

Figure D.1 — Example of a graph for residue evaluation

As composition, volume as well as handling of dilutions used for calibration are identical to those used for extracting the indicators (see D.2.2 and D.2.3), the spectrophotometer readings received during both procedures will be correspondent. This means that the axis of the diagram in Figure D.1 representing the formaldehyde concentration in microgram (µg) per 50 ml sample for calibration, can also represent the total amount of formaldehyde residues in µg in a 50 ml indicator extraction, i. e. the total amount of formaldehyde residues absorbed by a filter indicator.

EXAMPLE The slope of the straight line received by the calibration procedure according to D.2.4.2 is 818,2µg/E_{560} as shown in Figure D.1. By measuring a filter indicator extraction sample as described in D.2.2, the spectrophotometer reading is E_{560} = 0,1203. The residues of the filter indicator then can be read off in the graph or be calculated to 818,2 x 0,1203 = 98,43 µg formaldehyde.

Annex E
(informative)

Formaldehyde residues on medical devices

E.1 Assumptions for calculating limits for formaldehyde residues on medical devices

At present very little data are available on hazards to the patient regarding exposure to formaldehyde residuals on sterilized medical devices by other exposure routes than inhalation or contact with intact skin. The basis for calculations underlying the requirements of this standard regarding formaldehyde residues on sterilized medical devices are presented in the Dutch RIVM-report 710401018:1992 [12]. The limit values from the Netherlands in Table E.1 are based on data on LD_{50} values for a number of animal species and a number of exposure routes. LD_{50} values for inhalation and for the IV route were similar, and lower than for the oral or dermal exposure routes. The calculations for the limit for limited exposure through the inhalation or IV route, and through the oral or dermal route, were based on the lowest LD_{50} values in the range for the different exposure routes, and on a safety margin of 250 for translation of acute data from animals to one-time exposure in humans.

Table E.1 — References

Country	Exposure route	Limit value	Reference
NL	Intravenous exposure (and inhalation) Other	16,8 mg 28 mg	RIVM-report 710401018:1992, see [12]
US	Hemodialyzers	5 ppm	ANSI/AAMI RD 47:1993, see [1]
EP	Vaccines	0,2 g/l (200 ppm)	European Pharmacopoeia, see [6]

The data presented in the table above are used as a reasonable assumption to establish requirements for a test method that should secure the sterilizer to have a process not giving too high residuals when tested according to this standard.

NOTE The mean limit value set in 6.2 of this standard (200 µg) is approximately 80 times lower than the limit for intravenous exposure referred to in the table above. This safety margin has been selected to compensate for the simultaneous use of more than one device on the patient, and to the use of the device in the treatment of neonates.

E.2 Determination of formaldehyde residuals in sterilized goods

E.2.1 General

The method on determination of formaldehyde residuals in sterilized filter indicators in Annex D is based on a general procedure for determination described by V. Handlos, see [9], [10] and [11].

NOTE For general guidance on environmental aspects see Annex F.1.

The common purpose of both analyses is to determine the total amount of formaldehyde and its polymers in medical devices, which have been sterilized.

Most medical devices, which are sterilized by means of formaldehyde, consist of various types of plastics, various rubber materials, glass and metal. The residuals of formaldehyde may appear as absorbed or adsorbed formaldehyde or as polymerizate on the surface of the sterilized devices.

Porous materials such as textiles and paper have been shown to absorb a considerably higher amount of formaldehyde than e. g. plastics, glass or metal, which result in an increased retention ability for those porous materials. If setting an index Figure 1 for the formaldehyde retention ability of filter paper, the table below can give guidance for different material characteristics.

Table E.2 — Approximate residual figures compared to filter paper [11]

Material	Approximate residual figures compared to filter paper
Filter paper	1,0
Polyester fibres	1,3
Cotton linen	0,65
Polyamid 6	0,8
Polyethylene	0,4
Polypropylene	0,1
Polymethyl methacrylate	0
Cellulose acetate	0,15
Butyl rubber	1,1
Aluminium foil	0
Copper foil	0
Stainless steel	0,1

EXAMPLE The figure 0,1 for polypropylene indicates 10 times less retention ability than for filter paper.

E.2.2 Test methods

To simulate the absorption of formaldehyde into various types of materials, the method used for testing desorption efficiency at LTSF sterilizers specifies a filter paper as an absorbent indicator. As porous materials such as textiles and paper are considered to be the “worst case” regarding absorption and retention characteristics, the choice of the filter paper as indicator is considered to be the most practical alternative. In order to maintain a good reproducibility, requirements for a specific filter paper quality have been established (see C.5). A sterilizer desorption test procedure using filter paper indicators should be performed as described in A.3.

Additionally, desorption testing using medical products and/or a process challenge device can be of interest e. g. during validation. Independently of using the standardized filter paper method or if testing with medical products, the method for the determination of residual contents described in D.1 and D.2 can be used. Applicable medical products can then be replaced by the filter indicator and be extracted after sterilization. A non-sterilized medical product should be extracted in parallel with the sterilized product as a blank sample.

Since polymerized formaldehyde is not readily soluble in water, the method in D.2 uses 0,2 mol/l NaOH as extraction solution, whereby paraformaldehyde is depolymerized to formaldehyde. The amount of formaldehyde is then determined by the reaction between formaldehyde and chromotropic acid. The absorption is determined by a double ray spectrophotometer at a wavelength of 560 nm compared to a blank test extraction.

Annex F
(informative)

Environmental aspects

F.1 Environmental aspects regarding the life cycle of LTSF sterilizers

Environmental aspects covered by this standard are summarised in Table F 1.

F.2 Formaldehyde (brief description)

Formaldehyde is a colourless, toxic gas, highly soluble in water and commercially available as a 35 % solution called formalin. This solution is a clear, colourless liquid, with a highly irritating smell and “burning” taste that effects mucous membranes.

Formaldehyde solutions are normally used in medical environments as in autopsy, surgical and pathology departments, and in some extent in dermatology and X-ray departments.

The fact that formaldehyde is highly soluble in water is e. g. at sterilizers used to form a handy and efficient sterilant, as well as to dilute the process residuals in process water before disposal, into concentrations regarded as less harmful to the environment.

F.3 Environmental impact

Formaldehyde occurs naturally in most living creatures and is a vital part of our ecology. Formaldehyde is commercially widely used in different materials. It is produced from methanol and is environmentally bio-degradable according to the following formula chain:

CH_3OH(methanol) - HCHO(formaldehyde) - HCOOH(formic acid) - CO_2 + H_2O(carbon dioxide + water).

Formaldehyde solutions are known to be toxic, irritating and allergenic. They are also suspected to have carcenogenic effect on humans at long term exposure.

The low level of airborn concentration needed to detect formaldehyde at inhalation normally limits the possibility of unconscious exposure to harmful concentrations [7].

EXAMPLES FROM LITERATURE

— 0,05 ppm can normally be smelled;

— 0,01 ppm to 1,2 ppm can irritate the eyes;

— 0,5 ppm is in some countries regarded as a full-day working limit;

— 0,05 ppm to 1,2 ppm can irritate your nose;

— 1,0 ppm is in some countries regarded as a maximum level for 15 min;

— 4,0 ppm normally brings tears into the eyes.

National regulations can specify limits for the exposure of humans to airborn formaldehyde concentrations.

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

Environmental aspects (Inputs and Outputs)		Product life - cycle			
		Production and reproduction **Stage A**[a] addressed in clause	**Distribution (including packaging)** **Stage B**[a] addressed in clause	**Use** **Stage C** addressed in clause	**End of life** **Stage D** addressed in clause
1	Resource use	Introduction A.1 B.3.1	Introduction	Introduction A.1 B.3.1	Introduction 9.2
2	Energy consumption	Introduction A.1 B.3.1	Introduction	Introduction 9.2 A.1 B.3.1	–
3	Emission to air	Introduction A.1 B.3.1	Introduction	Introduction 4.2.4.1 4.2.6.1 5.3.1 5.3.3 5.3.4 5.3.5 5.3.7 6.2 9.2 9.5 10.7 10.8 A.1 B.3.1	Introduction 9.2
4	Emission to water	Introduction A.1 B.3.1	Introduction	Introduction 4.2.4.1 4.2.4.2 4.2.5.1 5.3.4 5.3.5 9.2 9.5 10.7 A.1 B.3.1	Introduction 9.2
5	Waste	Introduction A.1 A.2.2.2 A.3.6.1 A.3.3 D.2.1 B.3.1	Introduction 9.1	Introduction 9.2 9.3 9.5 A.1 A.2.1.2 A.2.2.2 A.3.3 B.1 D.2.1	Introduction 9.2

6	Noise	–	–	Introduction 7	–
7	Migration of hazardous substances	Introduction A.1 B.3.1 D.2.1	–	Introduction 4.1.1.1 4.2.2.1 4.2.4.1 5.3.1 5.3.3 5.3.4 5.3.5 5.3.6 5.3.7 5.3.1 6.2 A.1 B.3.1 D.2.1	Introduction 9.2
8	Impacts on soil	–	–	–	Introduction 9.2
9	Risks to the environment from accidents or misuse	Introduction	–	Introduction 4.2.2.2 4.2.4.1 4.2.4.2 4.2.5.2 4.2.6.2 4.3.2.2 4.3.2.4 4.3.2.6 4.3.4.1 4.3.4.6 4.3.5.4 5.1.3 5.2.1 5.3.2 5.3.7 5.4.2 5.5.5 5.5.8 8.3 9.2 10.3 10.5 D.2.1	Introduction 9.2
[a] Several common references in stage A and C above are made regarding testing as testing procedures are requested by this standard during both stages of the life cycle (see test programme in Annex B).					

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 CENELEC 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 as amended by 2007/47/EC on medical devices.

General Guidance:

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**
6.1.1.7, 6.2, 10.3, Annex E	7.2	See Note of general guidance. Covered in respect of design and manufacturing only. Including reference to EN 61010-1:2010, 5.4.4, 13.1 and 13.2.
4.1, 4.2.3, 4.2.7, 9.3 e), 10.4.2, 10.5, Annex E, Annex F	7.3, 1st part	Including references to EN 764-7, EN 13445 (series), EN 14222, EN 61010-1:2010, 11.1, 11.2, and EN 61010-2-040:2005, 5.4.3.
	7.3, 2nd part	Equipment is not intended to administer medicinal products.
	7.4	Equipment is not likely to incorporate medicinal products.
4.1.3, 4.2.3, 4.2.4, 4.2.5, 4.2.6, 5.2, 5.5, 6.1.1.7, 6.2, 10.3, 10.4, 10.8, Annex E,	7.5, 1st paragraph	See Note of general guidance. Leaking also addressed by references to EN 764-7, EN 14222 and EN 61010-1:2010, 11.3,11.4 and 13.1.
	7.5, 2nd and 3rd paragraph	Not likely to apply.
4.2.3, 4.2.4, 4.2.5, 4.2.6, 5.3.1, 5.5, 10.3, 10.4, 10.5, 10.6	7.6	See Note of general guidance. Air leakage and contaminants in the sterilant or steam can compromise the process.
	8	Sterilization of sterilizers is unlikely.
4.1.5, 4.2, 9.2, 9.3, 9.6, 10	9.1	
4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.2.6, 9.2, 10.3, 10.4, 10.8	9.2, 1st and 2nd dash	See Note of general guidance. Including references to EN 764-7, EN 13445 (series), EN 14222 and EN 61010-1:2010, 1.4 and Clause 7 and

		EN 61326-1.
	9.2, 3rd and 4th dash	Not likely to apply.
4.2.2, 10.3, 10.7, 10.8, Annex F	9.3	See Note of general guidance
	10	Not likely to apply, see MEDDEV 2.1/5.
4.2.2	11.1	Including references to EN 61010-1:2010, Clause 5, 12.1 and EN 61326-1.
	11.2, 11.3, 11.4, 11.5	LTSF-sterilizers are unlikely to emit, intended or unintended, hazardous or ionizing radiation
4.2.1, 4.2.2, 4.3.7, 5.1, 5.2, 5.3, 5.4, 6.1	12.1 12.1a	See Note of general guidance. Including references to EN ISO 14971 and EN 61010-2-040:2005, 7.104 and 14.104. State of the art comprehends many standards; notes refer to EN ISO 12100, EN ISO 13849, EN 61508 (series), EN 62061 and EN 62304.
	12.2 12.3 12.4	Equipment is likely to be installed distant from persons undergoing medical examination or treatment.
4.2.2	12.5	See Note of general guidance Reference to EN 61326-1.
4.2.2	12.6	See Note of general guidance Reference to EN 61010-1:2010, clauses 1, 2, 3, 4, 5, 6, 9, 10, 11, 14, 15.
4.1.3, 4.2.2.2, 4.2.3, 4.2.6, 4.2.8, 9.2 m)	12.7.1	See Note of general guidance. EN 61010-1:2010 applies, reference is made to Clauses 7, 8 enclosure, 14.1 components general, Clause 15 interlocks, EN 61010-2-040:2005, 13.1.102
7.2	12.7.2	
4.2.1, 7, 9.2 g)	12.7.3	See Note of general guidance. EN 61010-1:2010 applies, reference is made to 12.5.
4.1.5, 4.2.4, 4.2.7, 10.2, 10.7	12.7.4	See Note of general guidance
4.1.4, 4.2.2, 4.2.4, 4.2.7	12.7.5	EN 61010-1:2010, Clause 10; Note in 10.1 refers to EN 563 (replaced by EN ISO 13732-1)
	12.8	Supply of patient with energy or substances by a sterilizer is unlikely.
4.3, 5.4.2, 5.5, 8.6, 9.3	12.9	Including reference to EN 61010-2-040:2005, 5.1.5.1.
4.3.1, 4.3.8, 8, 9	13.1	Including reference to EN 1041 and EN 61010-2-040:2005, 5.1, 5.2, 5.3, 5.4.101.2 and 14.103.
8.4, 8.6 h)	13.2	Reference to EN ISO 15223-1, EN 1041 and EN 61010-1:2010, 5.1.1.
8.6 a), b), d), 8.2	13.3 a), b), d), i)	

	13.3 c), e), f), g), h), m), n)	Not likely to apply.
8.6 g), h)	13.3 j)	Including reference to EN 1041 and EN 61010-2-040:2005, 13.2.2 and 14.103.
8.5	13.3 k)	Including reference to EN 13445 (series) and EN 61010-1:2010, 5.1, 5.2 and 5.3.
8.6 f)	13.3 l)	
	13.4	Not likely to apply
9.3 e), 10.3	13.5	
8, 9	13.6 a)	Including reference to EN 1041, EN 13445 (series) and EN 61010-1:2010, 5.1, 5.2 and 5.3.
9.3	13.6 b)	
4.2.8, 9.2, 9.5, 10	13.6 c)	Including reference to EN 764-7 and EN 61010-1:2010, 5.4.
9.5	13.6 d)	Including reference to EN 61010-1:2010, 5.4.4 and 5.4.5.
	13.6 e), f), g), h), j), k), l), m), n), o), p)	Not likely to apply.
9.2	13.6 i)	
9.3 p)	13.6 q)	

WARNING — Other requirements and other EU Directives and Regulations 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**
4.1.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5, 9.2, 9.3, 10.3	1.1.3	Including reference to EN 61010–2-040:2005 13.1, 13.101, 13.102, and EN 14222:2003, 9.4, 9.6, 9.8 to 9.12
4.3.1, 4.3.7, 9.2 o), 10.9	1.1.4	
4.2.1, 4.2.3, 4.2.9, 8.1, 8.2	1.1.5	
4.2.1, 4.2.2, 4.2.8, 4.3.7, 5.1.1, 5.1.2, 5.2, 5.4, 5.5, 9.1, 9.3	1.1.6	Including reference to EN 61010–1:2010, 7.3.5 and Clause 16, and EN 61010–2-040:2005, 7.4.101
4.2.2.1, 6.2, 9.2, 9.3, 10.3, 10.7, 10.8, Annex E, F.3	1.1.7	Including reference to EN 61010–2-040:2005, 13.1, 13.1.101, 13.1.103, 13.2.102, 13.101
4.1.3, 4.2.2, 4.2.3, 4.3.1, 5.1, 5.2, 5.3, 5.4, 5.5	1.2.1	Including reference to EN 61010–1:2010, 4.3.1, Clauses 6, 7, and EN 61010–2-040:2005, 7.1.101, 7.5.101, 7.101, 7.104, Clause 8, 9.5.4, 11.105, 14.103, 14.104
4.2.2, 4.2.3, 4.3, 5.1.2, 5.4.2, 5.5, 8.6, 9.3	1.2.2	Including reference to EN 61010–2-040:2005, 5.1.5.1, 7.1.101, 7.101, 7.102, 7.104, 7.107, 11.102, 13.101.6 and 14.103
4.1.3, 4.2.1, 4.2.2.1, 5.2, 5.3, 5.4, 5.5, 9.3	1.2.3	Including reference to EN 61010–1:2010, Clause 15, EN 61010–2-040:2005, 7.1.101, 7.104, 7.107, 11.105 and 14.103
4.2.2.1, 4.2.3, 4.3, 4.3.7, 5.3, 5.4	1.2.4	Including reference to EN 61010–2-040:2005, 5.4.3, 6.11.1, 6.11.4.2 and 7.1.101
4.2.2.1, 4.3, 5.1, 5.3, 5.4, 5.5, 9.3	1.2.5	Including reference to EN 61010–2-040:2005, 13.1.102, 13.101.3 and 14.103
4.2.2.1, 4.2.3, 5.1, 5.3, 5.5	1.2.6	Including reference to EN 61010–2-040:2005, 4.4.2.102, 4.4.2.103, 6.101, 7.1.101, 7.7, 7.101, 7.104, 9.4, 11.103, 13.101.6, 14.103 and 14.104
4.2.2.1, 4.2.9, 8.1, 8.2, 9.2	1.3.1	Including reference to EN 61010–1:2010, 7.5, EN 61010–2-040:2005, 5.4.101.2, 7.4, 7.101 and 7.104

4.1.1, 4.2.2.1, 4.2.3, 4.2.4, 4.2.7, 9.3, 9.5	1.3.2	Including reference to EN 61010–1:2010, 7.5, Clause 8, 11.2, 11.7, 14.1 and EN 61010–2-040:2005, 5.4.5, 7.4
4.2.2.1,	1.3.3	Including reference to EN 61010–1:2010, 7.5, 7.7 and EN 61010–2-040:2005, 7.4.101
4.2.2.1	1.3.4	Including reference to EN 61010–1:2010, 7.3
4.2.2.1, 5.1, 5.3, 5.4	1.3.6	Including reference to EN 61010–2-040:2005, 14.103
4.1.3, 4.2.2.1, 4.2.2.2, 4.2.7, 5.4, 5.5, 8.6, 9.3, 9.5	1.3.7	Including reference to EN 61010–1:2010, 6.4.2, 7.3.2 b), 7.3.4, 7.3.5, Clause 8, 10.1, 13.1, 14.1 and EN 61010–2-040:2005, 7.1.101, 7.102, 7.101, 7.104
4.2.1, 4.2.2.1, 4.2.7	1.3.8	Including reference to EN 61010–1:2010, 7.3.2, see also EHSR 1.4.2.1 and 1.4.3
4.2.2.1	1.3.9	Including reference to EN 61010–1:2010, 7.3.4, and EN 61010–2-040:2005, 7.4.101, 7.101 c), 7.102
4.2.2.1, 4.2.7	1.4.1	Including reference to EN 61010–1:2010, Clause 8
4.2.2.1, 4.2.7	1.4.2	Including reference to EN 61010–1:2010, 7.3.2
4.1.3, 4.2.2.1	1.4.3	Including reference to EN 61010–2-040:2005, 7.101, 7.104 and 10.1
4.2.2.1	1.5.1	Including reference to EN 61010–1:2010, Clauses 5, 6 and Annexes D, H, K
4.2.2.1, 4.2.2.3	1.5.2	Including reference to EN 61010–1:2010, 6.3, 14.8 and EN 61326–1
4.2.2.1, 4.2.3, 4.2.4	1.5.3	Including reference to EN 61010–2-040:2005, 4.4.2.103, 5.4.3, 11.102 and 11.103
4.2.2.1, 4.2.4, 4.2.8, 8.5, 9.1, 9.2, 9.5, 10	1.5.4	Including reference to EN 61010–1:2010, 5.1, 5.4.5, 6.6, 6.10 and Clause 14
4.1.4.2, 4.2.2.1	1.5.5	Including reference to EN 61010–1:2010, 10.1
4.2.2.1, 4.2.3	1.5.6	Including reference to EN 61010–1:2010, Clause 9, and EN 14222
4.1.3, 4.2.2.1, 4.2.5, 5.3, 5.5, 6.2, 9.2, 9.3, 10.3, 10.7, 10.8,	1.5.13	Including reference to EN 61010–2-040:2005, 11.3,

Annex E, Annex F		13.1, 13.1.101 and 13.101.3
4.1.3, 4.2.2.1, 4.2.7	1.5.14	Including reference to EN 61010–2-040:2005, 7.101, 7.102 and 7.107
4.1.3.9, 4.1.5, 4.2.2.1, 4.2.7, 4.3.1, 5.4.1, 9.1, 9.2, 9.3	1.6.1	Including reference to EN 61010–2-040:2005, 5.4.3, 5.4.5, 5.4.101.2, 6.11, 7.3.2 and 14.103
4.1.3; 4.1.5.1; 4.2.2.1, 4.2.7, 4.3, 5.5, 9.2 a)	1.6.2	Including reference to EN 61010–1:2010, 7.3.5, EN 61010–2-040:2005, 5.4.5 and 7.102
4.2.2.1, 9.2, 10	1.6.3	Including reference to EN 61010–1:2010, 6.11 and EN 61010–2-040:2005, 5.4.3
4.1.3, 4.2.2.1, 4.2.3, 4.2.7, 5.3, 5.4, 5.5	1.6.4	Including reference to EN 61010–2-040:2005, 14.103, EN 13445-3:2012, Annex C, and EN 14222:2003, 9.5
4.1.1, 4.1.3, 4.2.2.1, 4.2.4, 5.3.5, 5.3.7, 5.5, 6.2, 9.3	1.6.5	Including reference to EN 61010–1:2010, 6.2, EN 61010–2-040:2005, 13.101
8, 9.1	1.7.1	Including reference to EN ISO 15223-1 and EN 1041
4.2.1, 4.3, 5.5.2, 8.5, 9.1	1.7.1.1	Including reference to EN 61010–2-040:2005, 5.1, 5.2, 5.4.1, 5.4.4, 5.4.101 and 14.103
4.2.2.1, 4.2.3, 4.3.1, 4.3.8, 5.5.2	1.7.1.2	Including reference to EN 61010–2-040:2005, 11.102, 11.105, EN 13445-3:2012, EN 14222:2003, 9.4.3 and EN 764–7:2002, 9.5

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

Bibliography

EN 285:2006+A2:2009, *Sterilization - Steam sterilizers - Large sterilizers*

EN 1041, *Information supplied by the manufacturer of medical devices*

EN 1422:1997+A1:2009, *Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods*

EN 1837:1999+A1:2009, *Safety of machinery - Integral lighting of machines*

EN 10027-2, *Designation systems for steels - Part 2: Numerical system*

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

EN 13445-3:2012, *Unfired pressure vessels - Part 3: Design*

EN 60204-1, *Safety of machinery — Electrical equipment of machines — Part 1: General requirements (IEC 60204-1)*

EN 61508 (all parts), *Functional safety of electrical/electronic/programmable electronic safety-related systems (IEC 61508 all parts)*

EN 61508-1, *Functional safety of electrical/electronic/programmable electronic safety-related systems — Part 1: General requirements (IEC 61508-1)*

EN 61508-3, *Functional safety of electrical/electronic/programmable electronic safety-related systems — Part 3: Software requirements (IEC 61508-3)*

EN 62061, *Safety of machinery — Functional safety of safety-related electrical, electronic and programmable electronic control systems (IEC 62061)*

EN 62304:2006, *Medical device software - Software life-cycle processes (IEC 62304:2006)*

EN ISO 534, *Paper and board - Determination of thickness, density and specific volume (ISO 534)*

EN ISO 536, *Paper and board - Determination of grammage (ISO 536)*

EN ISO 2758, *Paper - Determination of bursting strength (ISO 2758)*

EN ISO 4017, *Hexagon head screws - Product grades A and B (ISO 4017)*

EN ISO 9000:2005, *Quality management systems - Fundamentals and vocabulary (ISO 9000:2005)*

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

EN ISO 13485:2012, *Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)*

EN ISO 13732-1, *Ergonomics of the thermal environment - Methods for the assessment of human responses to contact with surfaces - Part 1: Hot surfaces (ISO 13732-1)*

EN ISO 13849-2, *Safety of machinery - Safety-related parts of control systems - Part 2: Validation (ISO 13849-2)*

EN ISO 17665-1:2006, *Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)*

EN ISO 25424:2011, *Sterilization of medical devices - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424:2009)*

ISO 1762, *Paper, board and pulps — Determination of residue (ash) on ignition at 525 degrees C*

ISO 3781, *Paper and board — Determination of tensile strength after immersion in water*

ISO 8787, *Paper and board — Determination of capillary rise — Klemm method*

ISO/TS 11139:2006, *Sterilization of health care products — Vocabulary*

[1] *ANSI/AAMI RD 47 Reprocessing of hemodialyzers*. Association for the Advancement of Medical Instrumentation, Arlington, VA, 1993

[2] Directive 93/42/EEC of the European Parliament and of the Council of 14 June 1993 concerning medical devices

[3] Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment

[4] Directive 98/83/EC of the European Parliament and of the Council of 3 November 1998 on the quality of water intended for human consumption

[5] Directive 2006/42/EC of the European Parliament and of the council of 17 May 2006 on machinery, and amending Directive 95/16/EC

[6] European Pharmacopoeia, 2001

[7] GAMBLE J. Effects of formaldehyde on the respiratory system. In: *Formaldehyde toxicity*, (GIBSON J.E., ed.). Hemisphere Publishing Corporation, Washington, 1983, pp. 175–97.

[8] GÖMANN J., KAISER U., MENZEL R. Reaction Kinetics of the Low-Temperature-Steam-Formaldehyde (LTSF) Sterilization Process. *Central Service*. 2000, **8** (5) pp. 290–296

[9] HANDLOS V. Formaldehyde Sterilization, I. Determination of Formaldehyde Residuals in autoclaved Materials. *Arch. Pharm. Chem. (Kbh)*. 1977, **5** pp. 163–169

[10] HANDLOS V. Formaldehyde Sterilization, II. Formaldehyde-Steam Sterilization, the Process and it's Influence on the Formaldehyde Residuals. *Arch. Pharm. Chem. (Kbh)*. 1979, **7** pp. 1–11

[11] HANDLOS V. Formaldehyde Sterilization, III. The Behaviour of the loaded Autoclave and the Permeability of Plastic Materials to Formaldehyde Arch. *Pharm. Chem.* 1979, **7** pp. 12–18

[12] RIVM-report 710401018: Exploratory report Formaldehyde Slooff W; Bont PFH; Janus JA; Loos B, RIVM Bilthoven 1992

This page deliberately left blank

This page deliberately left blank

British Standards Institution (BSI)

BSI is the national body responsible for preparing British Standards and other standards-related publications, information and services.

BSI is incorporated by Royal Charter. British Standards and other standardization products are published by BSI Standards Limited.

About us

We bring together business, industry, government, consumers, innovators and others to shape their combined experience and expertise into standards -based solutions.

The knowledge embodied in our standards has been carefully assembled in a dependable format and refined through our open consultation process. Organizations of all sizes and across all sectors choose standards to help them achieve their goals.

Information on standards

We can provide you with the knowledge that your organization needs to succeed. Find out more about British Standards by visiting our website at bsigroup.com/standards or contacting our Customer Services team or Knowledge Centre.

Buying standards

You can buy and download PDF versions of BSI publications, including British and adopted European and international standards, through our website at bsigroup.com/shop, where hard copies can also be purchased.

If you need international and foreign standards from other Standards Development Organizations, hard copies can be ordered from our Customer Services team.

Subscriptions

Our range of subscription services are designed to make using standards easier for you. For further information on our subscription products go to bsigroup.com/subscriptions.

With **British Standards Online (BSOL)** you'll have instant access to over 55,000 British and adopted European and international standards from your desktop. It's available 24/7 and is refreshed daily so you'll always be up to date.

You can keep in touch with standards developments and receive substantial discounts on the purchase price of standards, both in single copy and subscription format, by becoming a **BSI Subscribing Member**.

PLUS is an updating service exclusive to BSI Subscribing Members. You will automatically receive the latest hard copy of your standards when they're revised or replaced.

To find out more about becoming a BSI Subscribing Member and the benefits of membership, please visit bsigroup.com/shop.

With a **Multi-User Network Licence (MUNL)** you are able to host standards publications on your intranet. Licences can cover as few or as many users as you wish. With updates supplied as soon as they're available, you can be sure your documentation is current. For further information, email bsmusales@bsigroup.com.

BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK

Revisions

Our British Standards and other publications are updated by amendment or revision.

We continually improve the quality of our products and services to benefit your business. If you find an inaccuracy or ambiguity within a British Standard or other BSI publication please inform the Knowledge Centre.

Copyright

Useful Contacts:

Customer Services
Tel: +44 845 086 9001
Email (orders): orders@bsigroup.com
Email (enquiries): cservices@bsigroup.com

Subscriptions
Tel: +44 845 086 9001
Email: subscriptions@bsigroup.com

Knowledge Centre
Tel: +44 20 8996 7004
Email: knowledgecentre@bsigroup.com

Copyright & Licensing
Tel: +44 20 8996 7070
Email: copyright@bsigroup.com

bsi.

...making excellence a habit.™