SLOVENSKI STANDARD
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Sterilizatorji za uporabo v medicini - Sterilizatorji z etilenoksidom - Zahteve in preskusne metode

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

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

Stérilisateurs a usage médical - Stérilisateurs a l'oxyde d'éthylene - Exigences et méthodes d'essai

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This European Standard was approved by CEN on 30 August 1997.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Contents

Foreword

This European Standard 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of an identical text or by endorsement, at the latest by March 1998, and conflicting national standards shall be withdrawn at the latest by March 1998.

This European Standard 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 standard.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European standard specifies requirements for ethylene oxide sterilizers working above or below atmospheric pressure. The specification describes minimum performance and construction requirements for ethylene oxide sterilizers in two types:

Type A – user programmable sterilizers;

Type B – sterilizers of limited size with one or more pre-set operating cycles.

Type A sterilizers are particularly suitable for industrial use when a sterilization cycle can be required that is specific to a limited range of medical devices.

Type B sterilizers are particularly suitable for use in the sterilization of heat labile medical devices processed in healthcare facilities. Users of ethylene oxide sterilizers in healthcare facilities should be particularly aware of the following:

a) the difficulty in validating and monitoring suitable cleaning processes prior to sterilization;

b) the difficulty in carrying out representative performance qualification studies for the wide variety of loading patterns that can be used;

c) the difficulty in carrying out meaningful bioburden studies on small numbers of widely differing medical devices to be sterilized (see EN 1174);

d) the problems associated with determining the levels of residual ethylene oxide and its reaction products when small numbers of widely differing medical devices are processed (see EN ISO 10993-7);

e) the need for specialist technical resource dedicated to the operation and maintenance of the equipment.

For Type B sterilizers, a standard biological performance test has been specified for the pre-programmed sterilization cycle(s). This is not equivalent to validation. Attainment of sterilization conditions should be assured by validation procedures. Appropriate procedures for validation and routine monitoring of ethylene oxide sterilization processes used in the manufacture of medical devices are described in EN 550.

It is essential that a sterilizer is used only for sterilizing the goods which are compatible with the sterilization process. Ethylene oxide sterilizers should not be used for sterilizing goods which can be steam sterilized.

For the routine monitoring of the efficacy of each sterilization cycle, it is demonstrated that the attained level of each cycle variable is meeting or exceeding the minimum value determined during validation. The instrumentation specified for the sterilizer is intended to allow adequate monitoring of all the physical variables. However the complexity of the ethylene oxide process is such that, with current monitoring and validation techniques, it is usually regarded as necessary to monitor each cycle with a number of biological indicators. Biological indicators suitable for this purpose are described in EN 866-1, EN 866-2 and prEN 866-8.

Ethylene oxide is a highly reactive chemical which can present a toxicity, flammability or explosivity hazard if incorrectly handled. Ethylene oxide sterilizers, whether employing pure ethylene oxide gas or a mixture of ethylene oxide with another gas, have the potential to cause a serious local environmental hazard. Careful consideration of ethylene oxide sterilizers is recommended if the equipment is to be operated safely.

The efficacy and/or efficiency of the ethylene oxide sterilization process can be affected by the physical condition of goods (temperature and humidity) immediately prior to being loaded into the sterilizer.

The efficacy of the process is also affected by the packaging used to wrap goods for sterilization. Suitable packaging materials and methods for the validation of novel packaging materials are described in the series of EN 868.

The safe use of products which have been sterilized by ethylene oxide can depend upon the adequate removal of residual ethylene oxide (and its reaction products) after the products are removed from the sterilizer. Appropriate procedures for the assessment are described in EN ISO 10993-7.

This standard has been prepared on the basis that every individual sterilizer will be subject to functional performance tests. Unless otherwise stated in this standard, compliance with the performance requirements is checked by visual inspection or direct measurement.

The test methods and requirements of this standard are equally applicable for assessing the functional performance of the sterilizer throughout its life.

Users of this European standard are advised to consider the desirability of third party certification for product conformity with this European standard, based on testing and continuing surveillance which can be coupled with surveillance of a supplier's quality system in accordance with EN ISO 9001.

Alternatively users of this European standard can wish to consider the desirability of assessment and registration of a supplier's quality systems in accordance with EN ISO 9001 by a third party certification body.

1 Scope

1.1 This European standard specifies the minimum performance requirements and test methods of two types of sterilizers employing ethylene oxide gas as the sterilant, either as a pure gas or in admixture with other gases (whether supplied ready mixed or mixed at the point of use) in a temporarily sealed chamber.

These sterilizers are intended to be used for medical, dental, pharmaceutical, veterinary and industrial or related purposes. The two types of sterilizers have been designated Type A and Type B respectively using the following criteria:

- Type A sterilizers are capable of being programmed by the user;
- Type B sterilizers are of limited size and provided with one or more pre-set operating cycles which cannot be varied by the user.

The clauses of this standard apply to both types of sterilizers unless it is specifically indicated within the clause that it applies only to one of the types in particular.

1.2 This standard includes minimum performance and construction requirements for sterilizers working above or below atmospheric pressure:

- to ensure that the process is capable of being used to sterilize medical products;
- for the equipment and controls necessary to permit validation and monitoring of the sterilization process.

1.3 This standard does not specify those tests which are necessary to determine the probability of a processed product being sterile, nor the routine quality control tests required prior to release of sterile product. These topics are addressed in EN 550.

1.4 This standard does not specify the procedures and equipment which can be used to improve the efficacy and/or efficiency of the process before or after the sterilization cycle.

1.5 Considerations of operator safety are addressed in EN 61010-1 + A2 and IEC 1010-2-042.

1.6 This standard is applicable when:

a) specified in a contract for supply of an ethylene oxide sterilizer;

or,

b) a sterilizer manufacturer declares compliance when intending to supply an ethylene oxide sterilizer.

This standard is not intended as a checklist for suitability of an existing ethylene oxide sterilizer when assessing compliance with EN 550.

2 Normative references

This European standard incorporates by dated or undated reference, provisions from other publications. The normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of the these publications apply to this European standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 866-1
Biological systems for testing sterilizers and sterilization processes – Part 1: General requirements

EN 866-2
Biological systems for testing sterilizers and sterilization processes – Part 2: Particular system for use in ethylene oxide sterilizers

EN 868-1
Packaging materials and systems for medical devices which are to be sterilized – Part 1: General requirements and test methods

prEN 868-4
Packaging materials for sterilization of wrapped goods – Part 4: Paper bags – Requirements and tests

prEN 868-5
Packaging materials for sterilization of wrapped goods – Part 5: Heat sealable pouches and reel material of paper and plastic film construction – Requirements and tests

EN 50081-1
Electromagnetic compatibility – Generic emission standard – Part 1: Residential, commercial and light industry

EN 50081-2
Electromagnetic compatibility – Generic Emission standard – Part 2: Industrial environment

EN 50082-1
Electromagnetic compatibility – Generic immunity standard – Part 1: Residential, commercial and light industry

EN 50082-2
Electromagnetic compatibility – Generic immunity standard – Part 2: Industrial environment

EN 60584-2
Thermocouples – Part 2: Toleranzen (IEC 584-2 : 1982 + A1 : 1989)

EN 60651 : 1994
Sound level meters (IEC 651: 1979 + A 1 : 1993)

EN 60751 + A2
Industrial platinum resistance thermometer sensors (IEC 751 : 1983 + A2 : 1995)

EN 60804 : 1994
Integrating-averaging sound level meters (IEC 804 : 1985 + A 1 : 1989)

EN 61010-1 + A2
Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements (IEC 1010-1 : 1990 + A1 : 1992, modified + A2 : 1995)

EN ISO 3746 : 1995
Acoustics – Determination of sound power levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane (ISO 3746 : 1995)

IEC 73
Basic and safety principles for man-machine interface, marking and identification – Coding principles for indication devices and actuators

IEC 1010-2-042
Safety requirements for electrical equipment for measurement, control and laboratory use – Particular requirements for autoclaves and sterilizers using toxic gas for the treatment for medical materials, and for laboratory processes

ISO 228-1
Pipe threads where pressure-tight joints are not made on the threads – Part 1: Dimensions, tolerances and designation

ISO 6780
General-purpose flat pallets for through transit of goods – Principal dimensions and tolerances

ISO 10012-1
Quality assurance requirements for measuring equipment – Part 1: Metrological confirmation system for measuring equipment

3 Definitions

For the purposes of this European standard, the following definitions apply:

NOTE: Where defined terms appear in the text of this standard, an alternative type face is used.

3.1 aeration: A part or parts of the *sterilization process* in which defined conditions are used such that ethylene oxide and its reaction products are desorbed from the *medical device*, and which can be performed within the *sterilizer* (see 3.18 *flushing stage*), within a separate *room* or *chamber* (see 3.13 *degassing*), or by a combination of the two.

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

3.3 air removal: Removal of air from the *sterilizer chamber* and *sterilization load* sufficient to achieve validated sterilization conditions.

3.4 automatic controller: Device that, in response to pre-determined *cycle variables*, operates the *sterilizer* sequentially through the required stages of the process.

3.5 biological indicator: An *inoculated carrier* contained within its primary pack ready for use. [EN 866-1]

3.6 chamber: Enclosed area which only accommodates sufficient product to fill the *sterilizer*. [EN 550]

NOTE: See also *sterilizer chamber* (3.48).

3.7 chamber pre-heating: The heating of the *sterilizer chamber* to a predetermined temperature prior to the commencement of *air removal*.

3.8 commissioning: Obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications and that it functions within pre-determined limits when operated in accordance with operational instructions. [EN 550] (See also *validation* (3.58)).

3.9 conditioning: Treatment of product within the *sterilization cycle*, but prior to *sterilant* admission, to attain a predetermined temperature and relative humidity throughout the *sterilization load*. [EN 550] (See also 3.28 *pre-conditioning*).

3.10 cycle complete: Indication that the *operating cycle* has been satisfactorily completed and that the load is ready for removal from the *sterilizer chamber*.

3.11 cycle monitoring: A function of the *automatic controller* to check the attainment or otherwise of the pre-set *cycle variables* essential to the efficacy of the *sterilization cycle*.

3.12 cycle variables: The physical properties, e. g. time, temperature, *sterilant* concentration, that influence the efficacy of the *sterilization cycle*.

3.13 degassing: The desorption of ethylene oxide and its reaction products from the load by defined treatment outside the *sterilizer* after completion of the *sterilization cycle* (see also 3.1 *aeration*).

3.14 double-ended sterilizer: *Sterilizer* in which there is a door at each end of the *sterilizer chamber*. [EN 285]

3.15 exposure time: Time for which the *sterilizer chamber* is maintained at the specified temperature, *sterilant* concentration, pressure and humidity. [EN 550]

3.16 fail safe: Attribute of *sterilizer* design, component or its associated services that minimizes a possible *safety hazard*. [EN 285]

3.17 fault: Recognition by the *automatic controller* that the pre-set *cycle variables* for the *sterilization cycle* have not been attained and that sterilization has been jeopardised.

3.18 flushing stage: The stage beginning at the end of the *sterilant removal stage*, when further *sterilant* is removed from the load and *chamber* by either:

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

or,

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

3.19 inoculated carrier: A carrier on which a defined number of test organisms has been deposited. [EN 866-1]

3.20 load heating: Treatment of the load within the *sterilizer*, prior to *sterilant* injection, designed to ensure that all parts of the load are heated to a pre-determined temperature. (See also 3.9 *conditioning*).

3.21 load humidification: Treatment of the load within the *sterilizer* prior to *sterilant* injection, designed to ensure that all parts of the load are in equilibrium with a predetermined relative humidity at a given temperature. (See also 3.9 *conditioning*).

3.22 loading door: The door in a *double-ended sterilizer* through which the load is put into the *sterilizer chamber* prior to sterilization. (See also 3.56 *unloading door*).

3.23 medical device: The definition given in EN 46001 applies.

3.24 operating cycle: The automatic sequence of operating stages performed in a *sterilizer*.

3.25 override: The means by which the *operating cycle* can be interrupted or modified as necessary.

3.26 parametric release: A means of deciding that product sterility has been attained using physical process data rather than the results of sample testing of *biological indicators*.

3.27 performance qualification: Obtaining and documenting evidence that the equipment as commissioned will produce acceptable product when operated in accordance with the process specification. [EN 550] (See also 3.58 *validation*).

3.28 pre-conditioning: Treatment of product prior to the *sterilization cycle* to attain a predetermined temperature and relative humidity throughout the *sterilization load*. [EN 550] (See also 3.9 *conditioning*).

3.29 pre-conditioning area; pre-conditioning chamber; pre-conditioning room: An enclosed space in which *pre-conditioning* takes place.

3.30 pressure vessel: A vessel describing the *sterilizer chamber*, jacket (if fitted), door(s) and components that are in permanently open connection with the *sterilizer chamber* where positive pressure or vacuum can be formed.

3.31 process challenge device: An object which simulates the worst case of conditions as they are given for the sterilizing agent(s) in the items to be sterilized. [EN 866-1]

NOTE 1: The device is so constituted that a *biological indicator* can be put in the place most difficult to reach by sterilising agent(s). The design of the *process challenge device* depends on the kind of goods to be sterilized and the sterilization procedure. The *biological indicator* should not interfere with the function of the *process challenge device*.

NOTE 2: In some *process challenge devices*, an *inoculated carrier* can be used instead of a *biological indicator*.

3.32 product compatibility: The ability of the *sterilization process* to achieve the intended results without detrimental effect on the product.

3.33 room: Enclosed area capable of holding more product than can be accommodated in the *sterilizer(s)* at any one time. [EN 550]

3.34 reference load: Specified *sterilization load* made up to represent the combination of products which are most difficult to sterilize.

3.35 re-validation: A procedure to confirm an established *validation*.

3.36 safety hazard: Potentially detrimental effect on persons or the surroundings arising directly from either the *sterilizer* or its load. [EN 285]

3.37 sterilant: The microbicidal moiety, e. g. ethylene oxide, in the physical form in which it is active.

NOTE: It can be used together with any diluent(s).

3.38 sterilant cartridge: A transportable, single-use, simple vessel for containing *sterilant* under pressure from which *sterilant* is delivered by puncturing the cartridge.

NOTE: See also Directive 87/404/EEC of 1987; Harmonisation of Laws on Simple *Pressure Vessels*.

3.39 sterilant cylinder: A transportable vessel for containing *sterilant* under pressure and equipped with a valve to control the delivery of *sterilant*.

3.40 sterilant exposure stage: The stage beginning with the attainment of the set operating pressure at the end of the *sterilant injection stage* and ending with the initiation of the *sterilant removal stage*.

3.41 sterilant injection stage: The stage beginning with the first introduction of *sterilant* into the *chamber* and ending when the set operating pressure has been attained.

3.42 sterilant injection time: Duration of the *sterilant injection stage*. [EN 550]

3.43 sterilant removal stage: The stage, beginning at the end of the *sterilant exposure stage*, during which *sterilant* is removed from the *chamber*, and to a limited extent from the load, by evacuation of the *chamber* to a pre-set pressure.

NOTE: The *sterilant removal stage* is followed by the *flushing stage* (see 3.18).

3.44 sterilant removal time: The duration of the *sterilant removal stage*.

3.45 sterilant tank: A fixed installation for the bulk storage of *sterilant* which is periodically replenished.

3.46 sterile: Condition of a *medical device* that is free from viable micro-organisms. [EN 556]

3.47 sterilizer: Apparatus designed to achieve sterilization. [EN 285]

3.48 sterilizer chamber: That part of the *sterilizer* which receives the *sterilization load*.

3.49 sterilization cycle: Automatic sequence of operating stages performed in a *sterilizer* for the purpose of sterilization. [EN 550]

3.50 sterilization load: Goods that are to be, are being or have been sterilized simultaneously in one *sterilizer chamber*.

NOTE: The *sterilization load* can contain more than one manufacturing batch or lot.

3.51 sterilization module: Rectangular parallelepiped of the dimensions 300 mm width x 300 mm height x 600 mm length for the purposes of sterilization.

3.52 sterilization process: The sequence of events to which a packaged *medical device* is exposed to achieve sterilization, including pretreatment, the *sterilization cycle* and post-treatment.

3.53 sterilization temperature: Minimum temperature of the *sterilization temperature band*. [EN 554]

3.54 sterilization temperature band: Range of temperatures, expressed as the *sterilization temperature* and the maximum allowable temperature which may prevail throughout the *sterilization load* during the *exposure time*.

NOTE: These temperatures are usually stated in whole degrees celsius.

3.55 total volume: The total internal volume of the *sterilizer chamber*.

3.56 unloading door: The door in a *double-ended sterilizer* which is opened only at the completion of a successful *sterilization cycle* to withdraw the load from the *chamber*. (See also 3.22 *loading door*)

3.57 usable sterilizer chamber space: Space inside the *sterilizer chamber* which is not restricted by fixed parts and which is consequently available to accept the *sterilization load*.

3.58 validation: Documented procedure for obtaining, recording and interpreting the data required to show that a process will consistently comply with pre-determined specifications. [EN 550]

NOTE: *Validation* is considered a total process which consists of *commissioning* (see 3.8) and *performance qualification* (see 3.27).

4 Symbols and abbreviations

EO	ethylene oxide
N	nitrogen
CO_2	carbon dioxide
RH	relative humidity
s	second
min	minute
h	hour
µm	micrometre
mm	millimetre
m	metre
l	litre
N	newton
g	gram
kg	kilogram

Pa	pascal
kPa	kilopascal

NOTE: All pressures given in kPa are absolute pressures.

W	watt
kW	kilowatt
kJ	kilojoule
°C	degree celsius
K	kelvin
bar	bar
mbar	millibar
EN	European standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
v/v	volume in volume dilution
m/m	mass in mass dilution
dB	decibel
lx	lux

5 Size

5.1 The size of the *usable sterilizer chamber space* shall be designated by reference to the principle dimensions, measured in metres (to three significant figures).

In addition, for *sterilizers* up to 8000 l, the number of *sterilization modules* that can be accommodated in the *usable sterilizer chamber space* shall be stated (in integral numbers). For *sterilizers* of *usable sterilizer chamber space* greater than 8000 l, the number of pallets of plan dimensions (1200 mm x 1000 mm) and (1200 mm x 800 mm) conforming to ISO 6780 that can be accommodated shall be stated; the manufacturer shall also state the maximum height of a loaded pallet that can be accommodated.

5.2 In order to preclude adverse effects from the proximity of the *sterilization load* with the inside of the *sterilizer chamber*, the boundary of the *usable sterilizer chamber space* shall not be less than 15 mm from any heated surface and 30 mm from any unheated surface.

5.3 For Type B *sterilizers*, the volume of the *sterilizer chamber* shall not be greater than 1 m^3.

6 Vessels, materials and construction

6.1 General

6.1.1 A Council Directive on the approximation of the laws of the member states concerning pressure equipment (see 93/C246/01) and corresponding European Standards are in preparation (CEN/TC 54 and CEN/TC 269). Until European Standards on pressure equipment are published, the pressure equipment should comply with national regulations and standards applying in the country of intended use.

6.1.2 The manufacturer shall specify the maximum operating pressure available for selection by the user.

6.1.3 Some or all of the internal surfaces of the *sterilizer chamber* shall be heated. The heating system shall comply with 16.1.

6.1.4 The surfaces (including, for example, welds) which can come into contact with EO shall be of materials which, under the designed operating conditions:

a) are not corroded by EO, its diluent gases or steam;

b) will neither react with EO or other compounds found as contaminants of EO;

c) will not promote the polymerisation or decomposition of EO.

Vessels made of stainless steel, or mild steel clad with nickel or stainless steel where the cladding is not less than 8 % of the plate thickness, shall be deemed to meet these requirements. The thickness of any cladding shall be ignored when calculating the design strength.

NOTE 1: In the selection of materials for pressure parts and their integral attachments, due attention should be paid to the effects of galvanic attack and differential expansion when dissimilar metals are used in contact.

NOTE 2: Copper, copper alloys containing more than 65 % m/m copper, and unclad mild steel are not suitable for construction of the vessel where the EO gas may contain acetylene.

6.1.5 Untreated mild steel shall not be used for the construction of the interior of the *pressure vessel*.

6.2 Test connections

NOTE: The requirements of 6.2 do not preclude the combination of connections at one chamber entry port, using a T-fitting meeting the size requirements of the respective test connections and with the thermometry entry being a straight-in entry.

6.2.1 Thermometry entry connections

6.2.1.1 There shall be at least the following thermometry entry connections:

- one, if the *usable sterilizer chamber space* is less than 1 m^3;
- two, for *chambers* with a *usable sterilizer chamber space* up to 8 m^3;

NOTE: Additional connections can be required for *chambers* with a *usable sterilizer chamber space* above 8 m^3.

6.2.1.2 Each thermometry entry connection shall be located at least 100 mm from any internal or external obstruction.

6.2.1.3 Each thermometry entry connection shall terminate in a male pipe thread ISO 228-G1A and shall have a bore diameter of not less than 15 mm and not more than 20,5 mm. When the test connection is being used, it shall be closed with a sealing cap incorporating an O-ring seal.

6.2.1.4 The connection shall be permanently marked with the symbol "T" (i. e. temperature test).

6.2.2 Vacuum test connection

6.2.2.1 There shall be at least one vacuum test connection fitted to the *chamber*, or in direct connection with the *chamber*.

6.2.2.2 Each vacuum test connection shall terminate in a male pipe thread ISO 228-G1/2A and shall have a bore diameter of (6,0 ± 0,5) mm. When the test connection is being used, it shall be closed with a sealing cap incorporating an O-ring seal.

6.2.2.3 The connection shall be permanently marked with the symbol "V" (i. e. vacuum test).

6.2.2.4 The vacuum test connection shall be located at least 200 mm from any external obstruction if the total volume is greater than 1 m^3, otherwise 100 mm.

NOTE: This is to provide sufficient space for the connection, and reading, of a test instrument.