BS EN 556-2:2015

BSI Standards Publication

Sterilization of medical devices — Requirements for medical devices to be designated "STERILE"

Part 2: Requirements for aseptically processed medical devices

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National foreword

This British Standard is the UK implementation of EN 556-2:2015. It supersedes BS EN 556-2:2003 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

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

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

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

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Sterilization of medical devices - Requirements for medical devices to be designated ''STERILE" - Part 2: Requirements for aseptically processed medical devices

Stérilisation des dispositifs médicaux - Exigences relatives aux dispositifs médicaux en vue d'obtenir l'étiquetage " STÉRILE " - Partie 2 : Exigences pour les dispositifs médicaux soumis à un traitement aseptique

Sterilisation von Medizinprodukten - Anforderungen an Medizinprodukte, die als ''STERIL'' gekennzeichnet werden - Teil 2: Anforderungen an aseptisch hergestellte Medizinprodukte

This European Standard was approved by CEN on 24 July 2015.

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European foreword

This document (EN 556-2:2015) has been prepared by Technical Committee CEN/TC 204 “Sterilization of medical devices”, the secretariat of which is held by BSI.

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of an identical text or by endorsement, at the latest by March 2016, and conflicting national standards shall be withdrawn at the latest by March 2016.

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 556-2:2003.

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 Annexes ZA, ZB and ZC, which are integral parts of this document.

EN 556, *Sterilization of medical devices — Requirements for medical devices to be designated ''STERILE''*, is currently composed with the following parts:

— *Part 1: Requirements for terminally sterilized medical devices*;

— *Part 2: Requirements for aseptically processed medical devices* [this document].

The following amendments have been made in updating the document from EN 556-2:2003:

a) normative references have been updated;

b) terms and definitions have been aligned with ISO/TS 11139 and EN ISO 13408-1;

c) requirements on validation and routine control have been revised;

d) Table 1 and Table 2 on acceptance limits and actions for occurrence of non-sterile units in process simulations in initial performance qualification and in periodic requalification, respectively, have been added;

e) editorial revision according to the CEN Internal Regulations.

Annexes designated ‘informative’ are given only for information. In this standard Annexes ZA, ZB and ZC are informative.

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

Medical devices designated 'STERILE' are prepared using appropriate and validated methods. Whenever possible, sterile medical devices are terminally-sterilized using a properly validated and controlled sterilization process (see EN 556-1, EN ISO 11135, EN ISO 11137-1, EN ISO 14160, EN ISO 14937, EN ISO 17665-1, EN ISO 20857 and EN ISO 25424). When a medical device is intended to be sterile but cannot be terminally-sterilized, aseptic processing is the method of manufacture (see EN ISO 13408-1).

Aseptic processing necessitates that either:

a) the entire product is sterilized and then introduced into a sterilized package; or

b) components of the product are sterilized, then further processed/assembled, and the final product packed into a sterilized package.

Processing/assembly and packaging are carried out in a manner that minimizes the opportunity for items to become re-contaminated by carrying out these operations in a controlled environment in which microbial and particulate levels are maintained at or below defined limits and human intervention is minimized.

NOTE EN ISO 15223-1 specifies the label applied to aseptically processed medical devices as STERILE A.

1 Scope

This European Standard specifies the requirements for an aseptically processed medical device to be designated 'STERILE'.

NOTE For the purpose of the EU Directive(s) for medical devices (see Bibliography), designating that a medical device is 'STERILE' is permissible when a validated manufacturing and sterilization process has been applied. Requirements for validation and routine control of aseptic processes are specified in EN ISO 13408-1. Specific requirements for the aseptic processing of solid medical devices and combination products are specified in ISO 13408-7.

2 Normative references

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

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

EN ISO 11137-1:2015, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013)*

EN ISO 13408-2:2011, *Aseptic processing of health care products — Part 2: Filtration (ISO 13408-2:2003)*

EN ISO 13408-5:2011, *Aseptic processing of health care products — Part 5: Sterilization in place (ISO 13408-5:2006)*

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

EN ISO 14160:2011, *Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices (ISO 14160:2011)*

EN ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2009)*

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 20857:2013, *Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 20857:2010)*

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)*

3 Terms and definitions

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

3.1
aseptic processing
handling of sterile product, containers and/or devices in a controlled environment, in which the air supply, materials, equipment and personnel are regulated to maintain sterility

[SOURCE: EN ISO 13408-1:2015, 3.4]

3.2
bioburden
population of viable microorganisms on or in product and/or sterile barrier system

[SOURCE: ISO/TS 11139:2006, 2.2]

3.3
medical device
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]

3.4
performance qualification
PQ
process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification

[SOURCE: ISO/TS 11139:2006, 2.30]

3.5
process simulation
exercise that simulates the manufacturing process or portions of the process in order to demonstrate the capability of the aseptic process to prevent biological contamination

[SOURCE: ISO 13408-7:2012, 3.2]

Note 1 to entry: Other terms for process simulation include media fill, simulated process fill, simulated filling operation, broth trial, broth fill.

3.6
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]

3.7
sterility
state of being free from viable micro-organisms

[SOURCE: ISO/TS 11139:2006, 2.45]

3.8
sterile
free from viable microorganisms

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

3.9
terminally-sterilized
condition of a medical device which has been exposed to a sterilization process in a packaged or assembled form that maintains the sterility of the medical device or a defined portion thereof

[SOURCE: EN 556-1:2001, 3.5]

3.10
test for sterility
technical operation defined in an official Pharmacopoeia performed on product following exposure to a sterilization process

[SOURCE: ISO/TS 11139:2006, 2.53]

Note 1 to entry: For the purpose of this document, the official Pharmacopoeia that applies is the European Pharmacopoeia.

3.11
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: ISO/TS 11139:2006, 2.55]

4 Requirements

4.1 Validation and routine control

For an aseptically processed medical device, the following shall apply:

a) the manufacturing environment in which the aseptic process is conducted is specified and records demonstrating compliance with the specification throughout the conduct of the process are prepared and maintained;

b) the processes employed to sterilize product, components, equipment and packaging are validated and routinely controlled in compliance with EN ISO 11135:2014, EN ISO 11137-1:2015, EN ISO 14160:2011, EN ISO 13408-2:2011, EN ISO 13408-5:2011, EN ISO 14937:2009, EN ISO 17665-1:2006, EN ISO 20857:2013, or EN ISO 25424:2011 as applicable;

NOTE 1 Usually such sterilization processes are validated and routinely controlled to achieve a probability of a viable microorganism surviving on a sterilized item of 10^{-6} or less.

c) the requirements for the competence of personnel and methods for their training are specified and records demonstrating that the specified competence has been achieved are prepared and maintained;

d) the interventions that are permitted to occur in the aseptic process are identified, documented and validated;

e) records of all interventions occurring within the aseptic process are prepared and maintained;

f) process simulations are conducted initially in performance qualification and at a specified frequency thereafter;

g) when process simulations are undertaken, the observed frequency of occurrence of a non-sterile unit in initial performance qualification shall not be greater than that specified in Table 1 and thereafter not greater that specified in Table 2;

h) tests for sterility are carried out on product after aseptic processing and test results are interpreted against the acceptance criteria described in the European Pharmacopoeia. Records of the performance and outcomes of tests for sterility are prepared and maintained.

NOTE 2 EN ISO 13408-1 specifies detailed requirements for and guidance on the quality of the manufacturing environment, the training of personnel, the management of interventions, the performance of tests for sterility and the performance of process simulations.

NOTE 3 ISO 13408-7 specifies detailed requirements for and guidance on the quality of the manufacturing environment, the training of personnel, the management of interventions, the performance of tests for sterility and the performance of process simulations for medical devices and combination products.

NOTE 4 The target for process simulation is to obtain zero contaminated units. When a contaminated unit occurs, an investigation to identify its origin is carried out.

NOTE 5 For aseptically processed semi-solids, powders, solid medical devices, microspheres, liposomes and other formulations, evaluation by use of traditional process simulation using liquid media filling might not be possible. In such cases surrogate procedures that represent the operations as closely as possible might be developed and justified. These procedures might include processing of a sterile surrogate as normal with subsequent immersion in sterile media or some other means of simulation where sterility of the surrogate is determined after it has been subjected to the total aseptic process.

NOTE 6 Permission for acceptance of a frequency of occurrence of non-sterile units greater than that shown in Tables 1 and 2 or other approaches to demonstrate acceptable assurance of sterility for aseptically-processed medical devices can be sought through appropriate regulatory bodies. Such permission depends on the individual situation, including consideration of risk management activities undertaken by the manufacturer of the medical device (see EN ISO 14971).

Table 1 — Acceptance limits and actions for occurrence of non-sterile units in process simulations in initial performance qualification

Minimum number of simulations	Number of units filled per simulation	Number of contaminated units in any of the simulations	Number of simulations having contaminated units	Action
3	Less than 5 000	0	0	Accept
		1 or more	1 or more	Investigate, Implement corrective measures, repeat initial performance qualification
3	5 000 – 10 000	0	0	Accept
		1	1	Investigate, consider repeat of one process simulation
		More than 1	More than 1	Investigate, Implement corrective measures, repeat initial performance qualification
3	More than 10 000	0	0	Accept
		1	1	Investigate
		More than 1	More than 1	Investigate, Implement corrective measures, repeat initial performance qualification

Table 2 — Acceptance limits and actions for occurrence of non-sterile units in process simulations in periodic requalification

Minimum number of simulations	Number of units filled per simulation	Contaminated units	Action
2 per year [a]	Less than 5 000	0	Accept
		1	Investigate, repeat initial performance qualification
	5 000 – 10 000	0	Accept
		1	Investigate, consider repeat process simulation
		More than 1	Investigate, implement corrective measures, repeat initial performance qualification
	More than 10 000	0	Accept
		1	Investigate
		More than 1	Investigate, implement corrective measures, repeat initial performance qualification
[a] The process simulations cover all line configurations and shifts.			

4.2 Compliance

Compliance shall be demonstrated through provision of documentation and records of the validation and routine control of the aseptic process.

NOTE Evidence that an aseptically processed medical device is sterile comes from:

a) the validation of the aseptic process and subsequent re-qualifications that demonstrate the initial and continued acceptability of the process,

b) review of completeness and accuracy of information, gathered during routine monitoring and subsequent actions, that demonstrates a validated process has been delivered, and

c) the outcome of performance of the test for sterility.

4.3 Documentation and records

The documentation and records shall be retained as specified in EN ISO 13485:2012, 4.2.3 and 4.2.4.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on active implantable 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 90/385/EEC on active implantable medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with 90/385/EEC, as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with essential requirements 1, 4, 5, 8, 9 and 10 of the Directive.

NOTE 3 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Directive 90/385/EEC

Clause(s)/subclause(s) of this European Standard	Essential Requirements (ERs) of EU Directive 90/385/EEC	Qualifying remarks/Notes
Clause 4	7	This relevant Essential Requirement is only partly addressed in this European Standard. Design and packaging for maintenance of sterility during transportation and storage are not covered. Aspects of manufacture other than those related to the aseptic process are not covered.

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

Annex ZB
(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 on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZB.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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with 93/42/EEC, as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 When an Essential Requirement does not appear in Table ZB.1, it means that it is not addressed by this European Standard.

Table ZB.1 — Correspondence between this European Standard and EU Directive 93/42/EEC

Clause(s)/subclause(s) of this European Standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
Clause 4	8.1	This relevant ER is only partly addressed in this European Standard. Only aspects of the design of the aseptic process to reduce the risk of infection are covered.
Clause 4	8.3	This relevant ER is only partly addressed in this European Standard. Design and packaging for maintenance of sterility during transportation and storage are not covered. Aspects of manufacture other than those related to the aseptic process are not covered.
Clause 4	8.4	This relevant ER is only partly addressed in this European Standard. Aspects of manufacture other than those related to the attainment of sterility in the aseptic process are not considered.

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

Annex ZC
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC on *in vitro* diagnostic 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 98/79/EC on *in vitro* diagnostic medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZC.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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with 98/79/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with essential requirements Part A: 1, 2, 5; Part B: 1.2, 2, 3, 5, 6 and 7 of the Directive.

NOTE 3 When an Essential Requirement does not appear in Table ZC.1, it means that it is not addressed by this European Standard.

Table ZC.1 — Correspondence between this European Standard and Directive 98/79/EC

Clause(s)/subclause(s) of this European Standard	Essential Requirements (ERs) of EU Directive 98/79/EC	Qualifying remarks/Notes
Clause 4	B.2.1	This relevant ER is only partly addressed in this European Standard. Only aspects of the design of the aseptic process to reduce the risk of infection are covered.
Clause 4	B.2.3	This relevant ER is only partly addressed in this European Standard. Design and packaging for maintenance of sterility during transportation and storage are not covered. Aspects of manufacture other than those related to the aseptic process are not covered.
Clause 4	B.2.4	This relevant ER is only partly addressed in this European Standard. Only aspects of the design of the manufacturing process to attain the appropriate microbiological state are covered.

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

Bibliography

[1] EN 556-1:2001[1)], *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices*

[2] EN ISO 9001, *Quality management systems — Requirements (ISO 9001)*

[3] EN ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose (ISO 11137-2)*

[4] EN ISO 11137-3, *Sterilization of health care products — Radiation —Part 3: Guidance on dosimetric aspects (ISO 11137-3)*

[5] EN ISO 11737-1, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1)*

[6] EN ISO 11737-2, *Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2)*

[7] EN ISO 13408-1:2015, *Aseptic processing of health care products — Part 1: General requirements (ISO 13408-1:2008, including Amd 1:2013)*

[8] EN ISO 13408-3, *Aseptic processing of health care products — Part 3: Lyophilization (ISO 13408-3)*

[9] EN ISO 13408-4, *Aseptic processing of health care products — Part 4: Clean-in-place technologies (ISO 13408-4)*

[10] EN ISO 13408-6[2)], *Aseptic processing of health care products — Part 6: Isolator systems (ISO 13408-6)*

[11] EN ISO 14971, *Medical devices — Application of risk management to medical devices (ISO 14971)*

[12] 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)*

[13] EN ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664)*

[14] ISO 13408-7:2012, *Aseptic processing of health care products — Part 7: Alternative processes for medical devices and combination products*

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

[16] CEN ISO/TS 17665-2, *Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1 (ISO/TS 17665-2)*

1) This document is currently impacted by the corrigendum EN 556-1:2001/AC:2006, *Sterilization of medical devices — Requirements for medical devices to be designated 'STERILE' — Part 1: Requirements for terminally sterilized medical devices.*

2) This document is currently impacted by the amendment EN ISO 13408-6:2011/A1:2013, *Aseptic processing of health care products — Part 6: Isolator systems (ISO 13408-6:2005/Amd 1:2013).*

[17] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices

[18] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

[19] Council Directive 98/79/EC of 27 October 1998 on in vitro diagnostic medical devices

[20] European Pharmacopoeia 7

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