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BSI Standards Publication

Sterilization of health care products – Microbiological methods

Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 11737-2:2020. It is identical to ISO 11737-2:2019. It supersedes BS EN ISO 11737-2:2009, which is withdrawn.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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Sterilisation von Produkten für die Gesundheitsfürsorge - Mikrobiologische Verfahren - Teil 2: Prüfungen der Sterilität bei der Definition, Validierung und Aufrechterhaltung eines Sterilisationsverfahrens (ISO 11737-2:2019)

This European Standard was approved by CEN on 29 April 2020.

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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.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

This document (EN ISO 11737-2:2020) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with 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of an identical text or by endorsement, at the latest by November 2020, and conflicting national standards shall be withdrawn at the latest by November 2020.

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

This document supersedes EN ISO 11737-2:2009, with a revised European Foreword and European Annexes ZA, ZB and ZC, and additional European Annexes ZD and ZE.

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 the relationship with EU Directive(s) see informative Annex ZA, ZB, ZC, ZD and ZE which are an integral part of this document.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11737-2:2019 has been approved by CEN as EN ISO 11737-2:2020 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on active implantable medical devices [OJ L 189] aimed to be covered

This European standard has been prepared under a Commission's standardisation request M/023 to provide one voluntary means of conforming to essential requirements of 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 [OJ L 189].

Once this standard is cited in the Official Journal of the European Union under that Directive, 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 10of 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 Annex I of Directive 90/385/EEC [OJ L 189]

Essential Requirements (ERs) of Directive 90/385/EEC	Clauses of this EN	Qualifying remarks/Notes
7	4,5,6,7,8	This standard addresses the performance of tests of sterility in the definition, validation and maintenance of a sterilization process for medical devices. This relevant Essential Requirement is only partly addressed in this European Standard and only in conjunction with the applicable standard for validation and routine control of the sterilization process being employed. Design and packaging for maintenance of sterility during transportation and storage are not covered. Aspects of manufacture other than those related to the use of a test of sterility in the definition, validation or maintenance of a sterilization process are not covered.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products 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 [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/023 to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, 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 Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements (ERs) of Directive 93/42/EEC	Clauses of this EN	Qualifying remarks/Notes
8.3	4,5,6,7,8	This standard addresses the performance of tests of sterility in the definition, validation and maintenance of a sterilization process for medical devices. This relevant Essential Requirement is only partly addressed in this European Standard and only in conjunction with the applicable standard for validation and routine control of the sterilization process being employed. Design and packaging for maintenance of sterility during transportation and storage are not covered. Aspects of manufacture other than those related to the use of a test of sterility in definition, validation or maintenance of a sterilization process are not covered.
8.4	4,5,6,7,8	This relevant Essential Requirement is addressed only in regards to the use of a test of sterility in the definition, validation or maintenance of a sterilization process for the device. Aspects of manufacture other than those related to the use of a test of sterility in the definition, validation or maintenance of a sterilization process are not covered.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products 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 [OJ L 331] aimed to be covered

This European standard has been prepared under a Commission's standardisation request, M/252, concerning the development of European standards relating to in vitro diagnostic medical devices, to provide one voluntary means of conforming to essential requirements of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices [OJ L 331].

Once this standard is cited in the Official Journal of the European Union under that Directive, 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 and 5; Part B: 1.2, 2, 3, 5, 6, and 7of 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 Annex I of Directive 98/79/EC [OJ L 331]

Essential Requirements (ERs) of Directive 98/79/EC	Clauses of this EN	Qualifying remarks/Notes
B.2.3	4,5,6,7,8	This standard addresses the performance of tests of sterility in the definition, validation and maintenance of a sterilization process for medical devices. This relevant Essential Requirement is only partly addressed in this European Standard and only in conjunction with the applicable standard for validation and routine control of the sterilization process being employed. Design and packaging for maintenance of sterility during transportation and storage are not covered. Aspects of manufacture other than those related to use of a test of sterility in the definition, validation or maintenance of a sterilization process are not covered.
B.2.4	4,5,6,7,8	This relevant Essential Requirement is addressed only in regards to the use of a test of sterility in the definition, validation or maintenance of a sterilization process for the device.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

Annex ZD
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under a Commission's standardisation request to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117].

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZD.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, 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 Regulation (EU) 2017/745. This means that risks have to be 'reduced as far as possible', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'removed or minimized as far as possible', or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZD.1, it means that it is not addressed by this European Standard.

Table ZD.1 — Correspondence between this European standard and Annex I of Regulation (EU) 2017/745 [OJ L 117]

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
11.3	4,5,6,7,8	This standard addresses the performance of tests of sterility in the definition, validation and maintenance of a sterilization process for medical devices. It could also be applied in the development, validation and routine control of a process for attainment of a specific microbial state other than sterility. This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Packaging for maintenance of a specific microbial state during transportation and storage are not

		covered. Aspects of manufacture other than those related use of a test of sterility in attainment of a specific microbial state are not covered.
11.4 first sentence only	4,5,6,7,8	This standard addresses the performance of tests of sterility in the definition, validation and maintenance of a sterilization process for medical devices. This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Packaging for maintenance of sterility during transportation and storage are not covered. Aspects of manufacture other than those related to use of a test of sterility in definition, validation and maintenance of a sterilization process are not covered. Evidence that the integrity of the packaging is maintained to the point of use is not covered.
11.5	4,5,6,7,8	This standard addresses the performance of tests of sterility in the definition, validation and maintenance of a sterilization process for medical devices. This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Design and packaging for maintenance of sterility are not covered. Aspects of manufacture other than those related to use of a test of sterility in definition, validation and maintenance of a sterilization process are not covered.

WARNING 1: Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2: Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

Annex ZE
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered

This European standard has been prepared under a Commission's standardisation request to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/746 of 5 April 2017 concerning in vitro diagnostic medical devices [OJ L 117].

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZE.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, 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 Regulation (EU) 2017/746. This means that risks have to be 'reduced as far as possible', 'reduced to a level as low as reasonably practicable', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'prevented' or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 10, 11, 13, 15, 16, 17, 18 and 19 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZE.1, it means that it is not addressed by this European Standard.

Table ZE.1 — Correspondence between this European standard and Annex I of Regulation (EU) 2017/746 [OJ L 117]

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
11.2	4,5,6,7,8	This standard addresses the performance of tests of sterility in the definition, validation and maintenance of a sterilization process for medical devices. It could also be applied to the development or validation of a process for attainment of a specific microbial state other than sterility. This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Packaging for maintenance of a sterility or another specific microbial state during transportation and storage are not covered. Aspects of

		manufacture other than those related use of a test of sterility in attainment of a specific microbial state are not covered
11.3	4,5,6,7,8	This standard addresses the performance of tests of sterility in the definition, validation and maintenance of a sterilization process for medical devices. This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Packaging for maintenance of sterility are not covered. Aspects of manufacture other than those related to use of a test of sterility in definition, validation and maintenance of a sterilization process are not covered.

WARNING 1: Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2: Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This third edition cancels and replaces the second edition (ISO 11737-2:2009), which has been technically revised.

The main changes compared to the previous edition are as follows:

— addition of a requirement concerning the test samples and the interval of time between the manufacture of product and the exposure to the sterilizing agent being as short as possible;

— addition of a requirement about the samples staying immersed in the culture media and providing a rationale where this is not possible;

— provision of additional guidance regarding performing tests of sterility on packaging, clarifying that package testing is not typically done except when it is an integral part of the product;

— provision of additional guidance regarding what is meant by “controlled environment” for performing tests of sterility;

— provision of additional guidance to discuss circumstances where the method suitability test does not give acceptable results, stating that after multiple attempts to eliminate inhibitory substances, it is appropriate to accept a reduction of inhibitory substances, with an accompanying rationale and risk assessment;

— provision of guidance regarding identification of microbial growth in a test of sterility, saying generally for positive growth the microorganism(s) should be identified;

— provision of guidance regarding method suitability, saying that consideration should be given to periodically demonstrating ongoing method suitability in order to ensure that an accumulation of minor changes over time has not occurred;

— addition of a table to clarify where typical responsibilities reside for the manufacturer or the laboratory.

A list of all parts in the ISO 11737 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

A sterile medical device is one that is free from viable microorganisms. International Standards that specify requirements for validation and routine control of sterilization processes require, when it is necessary to supply a sterile medical device, that adventitious microbiological contamination of a medical device from all sources be minimized. Even so, medical devices produced under standard manufacturing conditions in accordance with the requirements for quality management systems (see, for example, ISO 13485) can, prior to sterilization, have microorganisms on them. Such products are non-sterile. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile products into sterile ones.

The kinetics of inactivation of a pure culture of microorganisms by physical and/or chemical agents used to sterilize medical devices can generally best be described by an exponential relationship between the numbers of microorganisms surviving and the extent of treatment with the sterilizing agent; inevitably this means that there is always a finite probability that a microorganism might survive regardless of the extent of treatment applied. For a given treatment, the probability of survival is determined by the number and resistance of microorganisms and by the environment in which the organisms exist during treatment. It follows that the sterility of any one item in a population subjected to sterilization processing cannot be guaranteed and the sterility of a processed population is defined in terms of the probability of there being a viable microorganism present on a product item.

Generic requirements of the quality management system for design and development, production, installation and servicing are given in ISO 9001 and particular requirements for quality management systems for medical device production are given in ISO 13485. The standards for quality management systems recognise that, for certain processes used in manufacturing, the effectiveness of the process cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of such a process. For this reason, sterilization processes are validated for use, the performance of the sterilization process is monitored routinely and the equipment is maintained.

International Standards specifying procedures for the development, validation and routine control of the processes used for sterilization of medical devices have been prepared [see ISO 11135, ISO 11137 (all parts), ISO 14937, ISO 14160, ISO 17665-1 and ISO 20857]. An element of validation might consist of exposing medical devices to the sterilizing agent with the extent of treatment being reduced relative to that which will be used in routine sterilization processing, in order to provide a knowledge of the resistance to the agent of the microbial contamination as it occurs naturally on medical devices. The reduced exposures applied in these instances are often called fractional exposures or verification doses. Subsequent to this reduced exposure, medical devices are subjected individually to tests of sterility as described in this document. Examples of the use of such tests are in:

a) establishing a dose for sterilization by radiation,

b) demonstrating the continued validity of an established sterilization dose, and

c) establishing a cycle for sterilization by evaluating the product's naturally occurring bioburden.

Product that has been exposed to a terminal sterilization process in its final packaged form has a very low probability of the presence of a viable microorganism; such as one in one million or 10^{-6}. As such, performing a test of sterility on product that has been exposed to the complete sterilization process provides no scientifically usable data and is not recommended.

Annex A of this document gives guidance on the techniques used and on practical aspects of the requirements.

INTERNATIONAL STANDARD ISO 11737-2:2019(E)

Sterilization of health care products — Microbiological methods —

Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

1 Scope

1.1 This document specifies the general criteria for tests of sterility on medical devices that have been exposed to a treatment with the sterilizing agent which has been reduced relative to that anticipated to be used in routine sterilization processing. These tests are intended to be performed when defining, validating or maintaining a sterilization process.

1.2 This document is not applicable to:

a) sterility testing for routine release of product that has been subjected to a sterilization process,

b) performing a test for sterility (see 3.12),

NOTE 1 The performance of a) or b) is not a requirement of ISO 11135, ISO 11137-1, ISO 11137-2, ISO 14160, ISO 14937, ISO 17665-1 or ISO 20857.

c) test of sterility or test for sterility for demonstration of product shelf life, stability and/or package integrity, and

d) culturing of biological indicators or inoculated products.

NOTE 2 Guidance on culturing biological indicators is included in ISO 11138-7.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
aseptic technique
conditions and procedures used to minimize the risk of the introduction of microbial contamination

[SOURCE: ISO 11139:2018, 3.16]