BS EN ISO 11135:2014+A1:2019
Incorporating corrigenda January 2015 and January 2020

BSI Standards Publication

Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices

Documents
Document Sharing Hub

Full document details: BS EN ISO 11135:2014+A1:2019

National foreword

This British Standard is the UK implementation of EN ISO 11135:2014+A1:2019. It is identical to ISO 11135:2014, incorporating amendment 1:2018. It supersedes BS EN ISO 11135:2014, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by A1 A1.

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.

© The British Standards Institution 2020
Published by BSI Standards Limited 2020

ISBN 978 0 539 12708 9

ICS 11.080.01

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 July 2014.

Amendments/corrigenda issued since publication

Date	Text affected
31 January 2015	Implementation of CEN Correction Notice 10 December 2014: the DOW has been corrected in the CEN European Foreword
30 November 2019	Implementation of ISO amendment 1:2018 with CEN endorsement A1:2019
31 January 2020	Implementation of CEN correction notice 11 December 2019: CEN Foreword to amendment A1 corrected and all tables replaced

Documents
Document Sharing Hub

Full document details: BS EN ISO 11135:2014+A1:2019

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11135:2014 +A1

November 2019

ICS 11.080.01

English Version

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)

Stérilisation des produits de santé — Oxyde d'éthylène — Exigences de développement, de validation et de contrôle de routine d'un processus de stérilisation pour des dispositifs médicaux (ISO 11135:2014)

Sterilisation von Produkten für die Gesundheitsfürsorge — Ethylenoxid — Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (ISO 11135:2014)

This European Standard was approved by CEN on 28 June 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

© 2014 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members

Ref. No. EN ISO 11135:2014+A1:2019: E

Documents
Document Sharing Hub

Full document details: BS EN ISO 11135:2014+A1:2019

European foreword

This document (EN ISO 11135:2014) 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 January 2015, and conflicting national standards shall be withdrawn at the latest by July 2017.

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

This document supersedes CEN ISO/TS 11135-2:2008, EN ISO 11135-1:2007.

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, ZB, 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, 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.

Endorsement notice

The text of ISO 11135:2014 has been approved by CEN as EN ISO 11135:2014 without any modification.

Foreword to amendment A1

This document (EN ISO 11135:2014/A1:2019) 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 Amendment to the European Standard EN ISO 11135:2014 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2020, and conflicting national standards shall be withdrawn at the latest by May 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 modifies EN ISO 11135:2014 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 relationship with EU Directive(s) and Regulation(s), see informative Annex ZA, ZB, ZC, ZD and ZE, which are an integral part of this document.

AVA Documents
Document Sharing Hub

Full document details: BS EN ISO 11135:2014+A1:2019

The following referenced documents are indispensable for the application of this document. For undated references, the edition of the referenced document (including any amendments) listed below applies. For dated references, only the edition cited applies. However, for any use of this standard within the meaning of Annex ZA, ZB, ZC, ZD or ZE, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this should be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 10012	EN ISO 10012:2003	ISO 10012:2003
ISO 10993-7	EN ISO 10993-7:2008	ISO 10993-7:2008
ISO 11138-1:2006	EN ISO 11138-1:2006	ISO 11138-1:2006
ISO 11138-2:2009,	EN ISO 11138-2:2009	ISO 11138-2:2009
ISO 11140-1	EN ISO 11140-1:2014	ISO 11140-1:2014
ISO 11737-1	EN ISO 11737-1:2018	ISO 11737-1:2018
ISO 11737-2	EN ISO 11737-2:2009	ISO 11737-2:2009
ISO 13485:2003/Cor 1:2009	EN ISO 13485:2016	ISO 13485:2016

NOTE Some standards normatively referred to by EN ISO 11135:2014/A1:2019 are undated. These referred standards also include normative references to other dated and undated standards. For undated normative references, it should always be assumed that the latest edition applies.

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 11135:2014/Amd 1:2018 has been approved by CEN as EN ISO 11135:2014/A1:2019 without any modification.

Documents
Document Sharing Hub

Full document details: BS EN ISO 11135:2014+A1:2019

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/BC/CEN/89/9 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 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

AVA Documents
Document Sharing Hub

Full document details: BS EN ISO 11135:2014+A1:2019

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	4,5,6,7,8,9,10,11,12	This standard provides requirements for the development, validation and routine control of a sterilization process for medical devices using ethylene oxide, including requirements that the sterilized medical device is safe and performs as intended after sterilization. This Essential Requirement is addressed only with regard to devices for which sterilization by ethylene oxide is appropriate. 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 sterilization by ethylene oxide 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.

AVA Documents
Document Sharing Hub

Full document details: BS EN ISO 11135:2014+A1:2019

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/BC/CEN/89/9 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 This Annex ZB is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZB.1, it means that it is not addressed by this European Standard.

AVA Documents
Document Sharing Hub

Full document details: BS EN ISO 11135:2014+A1:2019

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	4,5,6,7,8,9,10,11,12	This standard provides requirements for the development, validation and routine control of a sterilization process for medical devices using ethylene oxide, including requirements that the sterilized medical device is safe and performs as intended after sterilization. This Essential Requirement is addressed only with regard to devices for which sterilization by ethylene oxide is appropriate. 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 sterilization by ethylene oxide are not covered.
8.4	4,5,6,7,8,9,10,11,12	This relevant Essential Requirement is only partly addressed in this European Standard. This Essential Requirement is addressed only with regard to devices for which sterilization by ethylene oxide is appropriate. Aspects of manufacture other than those related to sterilization by ethylene oxide 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.

AVA Documents
Document Sharing Hub

Full document details: BS EN ISO 11135:2014+A1:2019

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 This Annex ZC is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZC.1, it means that it is not addressed by this European Standard.

Documents
Document Sharing Hub

Full document details: BS EN ISO 11135:2014+A1:2019

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	4,5,6,7,8,9,10,11,12	This standard provides requirements for the development, validation and routine control of a sterilization process for medical devices using ethylene oxide, including requirements that the sterilized medical device is safe and performs as intended after sterilization. This Essential Requirement is addressed only with regard to devices for which sterilization by ethylene oxide is appropriate. 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 sterilization by ethylene oxide are not covered.
B.2.4	4,5,6,7,8,9,10,11,12	This relevant Essential requirement is addressed only with regard to: sterilization, not covering other special microbiological state devices for which sterilization by ethylene oxide is appropriate

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.

AVA Documents
Document Sharing Hub

Full document details: BS EN ISO 11135:2014+A1:2019

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 This Annex ZD is based on normative references according to the table of references in the European Foreword, replacing the references in the core text.

NOTE 4 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	4,5,6,7,8,9,10,11,12	This standard provides requirements for the development, validation and routine control of a sterilization process for medical devices using ethylene oxide, including requirements that the medical device is safe and performs as intended after treatment. It could also be applied to the development, validation and routine control of a process for attainment of a specific microbial state other than sterility. This

Documents
Document Sharing Hub
Full document details: BS EN ISO 11135:2014+A1:2019

		General Safety and Performance Requirement is addressed only with regard to devices for which treatment by ethylene oxide is appropriate. This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Design and packaging for maintenance of a specific microbial state during transportation and storage are not covered. Aspects of manufacture other than those related to attainment of a specific microbial state by ethylene oxide are not covered.
11.4 first sentence only	4,5,6,7,8,9,10,11,12	This standard provides requirements for the development, validation and routine control of a sterilization process using for medical devices using ethylene oxide, including requirements that the sterilized medical device is safe and performs as intended after sterilization. This General Safety and Performance Requirement is addressed only with regard to devices for which sterilization by ethylene oxide is appropriate. This relevant General Safety and Performance 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 attainment of sterility ethylene oxide are not covered. Evidence that the integrity of the packaging is maintained to the point of use is not covered.
11.5	4,5,6,7,8,9,10,11,12	This standard provides requirements for the development, validation and routine control of a sterilization process for medical devices using ethylene oxide, including requirements that the sterilized medical device is safe and performs as intended after sterilization. This General Safety and Performance Requirement is addressed only with regard to

Documents
Document Sharing Hub
Full document details: BS EN ISO 11135:2014+A1:2019

		devices for which sterilization by ethylene oxide is appropriate. 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 attainment of sterility by ethylene oxide 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.

Documents
Document Sharing Hub

Full document details: BS EN ISO 11135:2014+A1:2019

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 This Annex ZE is based on normative references according to the table of references in the European Foreword, replacing the references in the core text.

NOTE 4 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	4,5,6,7,8,9,10,11,12	This standard provides requirements for the development, validation and routine control of a sterilization process for medical devices using ethylene oxide, including requirements that the medical device is safe and performs as intended after treatment. It could also be applied to the development, validation and routine control of a process for attainment of a specific microbial state other than sterility. This

AVA Documents Document Sharing Hub

Full document details: BS EN ISO 11135:2014+A1:2019

		General Safety and Performance Requirement is addressed only with regard to devices for which treatment by ethylene oxide is appropriate. This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Design and 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 to attainment of sterility or another specific microbial state by ethylene oxide are not covered.
11.3	4,5,6,7,8,9,10,11,12	This standard provides requirements for the development, validation and routine control of a sterilization process for medical devices using ethylene oxide, including requirements that the sterilized medical device is safe and performs as intended after sterilization. This General Safety and Performance Requirement is addressed only with regard to devices for which sterilization by ethylene oxide is appropriate. 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 attainment of sterility by ethylene oxide 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.

Documents
Document Sharing Hub

Full document details: BS EN ISO 11135:2014+A1:2019

Contents

Page

Foreword ... **xvii**

Introduction ... **xviii**

1 Scope ... **1**
1.1 Inclusions ... 1
1.2 Exclusions ... 1

2 Normative references ... **2**

3 Terms and definitions ... **3**

4 Quality management systems ... **10**
4.1 Documentation ... 10
4.2 Management responsibility ... 11
4.3 Product realization ... 11
4.4 Measurement, analysis and improvement — Control of nonconforming product ... 11

5 Sterilizing agent characterization ... **11**
5.1 General ... 11
5.2 Sterilizing agent ... 11
5.3 Microbicidal effectiveness ... 12
5.4 Material effects ... 12
5.5 Safety and the environment ... 12

6 Process and equipment characterization ... **12**
6.1 General ... 12
6.2 Process characterization ... 12
6.3 Equipment characterization ... 13

7 Product definition ... **14**
7.1 General ... 14
7.2 Product safety, quality and performance ... 15
7.3 Microbiological quality ... 15
7.4 Documentation ... 15

8 Process definition ... **15**

9 Validation ... **16**
9.1 General ... 16
9.2 Installation qualification, IQ ... 17
9.2.1 Equipment ... 17
9.2.2 Installation qualification ... 17
9.3 Operational qualification, OQ ... 17
9.4 Performance qualification, PQ ... 18
9.4.1 General ... 18
9.4.2 Performance qualification — Microbiological ... 18
9.4.3 Performance qualification — Physical ... 19
9.5 Review and approval of validation ... 20

10 Routine monitoring and control ... **22**

11 Product release from sterilization ... **23**

12 Maintaining process effectiveness ... **23**
12.1 General ... 23
12.2 Maintenance of equipment ... 24
12.3 Requalification ... 24
12.4 Assessment of change ... 24
12.5 Assessment of equivalence ... 25
12.5.1 Process Equivalence ... 25
12.5.2 Product ... 25

© ISO 2014 – All rights reserved

AVA Documents
Document Sharing Hub

Full document details: BS EN ISO 11135:2014+A1:2019

Annex A (normative) **Determination of lethal rate of the sterilization process — Biological indicator/bioburden approach** **26**

Annex B (normative) **Conservative determination of lethal rate of the sterilization process — Overkill approach** **27**

Annex C (informative) **Temperature sensors, RH sensors and biological indicator numbers** **29**

Annex D (informative) **Guidance on the application of the normative requirements** **32**

A1 **Annex E** (normative) **Single batch release** **74**

Bibliography **77**

© ISO 2014 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS EN ISO 11135:2014+A1:2019

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. 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. 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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 198, *Sterilization of health care products*.

ISO 11135:2014 cancels and replaces ISO 11135-1:2007 and ISO/TS 11135-2:2008, both of which have been technically revised and condensed into a single standard.

© ISO 2014 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS EN ISO 11135:2014+A1:2019

Introduction

A sterile medical device is one that is free of viable microorganisms. Medical devices produced under standard manufacturing conditions in accordance with the requirements for quality management systems (see for example ISO 13485) might, prior to sterilization, have microorganisms on them, albeit in low numbers. Such medical devices are non-sterile. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile medical devices 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 ethylene oxide (EO); 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 medical device 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 medical device.

ISO 11135 describes requirements that, if met, will provide an ethylene oxide sterilization process intended to sterilize medical devices, which has appropriate microbicidal activity. Furthermore, compliance with the requirements ensures that validations conducted following this International Standard will provide products that meet the defined requirements for sterile products with a high degree of confidence. The specification for this probability is a matter for regulatory authorities and can vary from country to country (see for example EN 556-1 and ANSI/AAMI ST67).

Generic requirements of the quality management systems 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 recognize that, for certain processes used in manufacturing or reprocessing, 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 monitored routinely and the equipment maintained.

Exposure to a properly validated, accurately controlled sterilization process is not the only factor associated with the provision of reliable assurance that the product is sterile and, in this regard, suitable for its intended use. Attention is therefore given to a number of considerations including:

— the microbiological status of incoming raw materials and/or components;

— the validation and routine control of any cleaning and disinfection procedures used on the product;

— the control of the environment in which the product is manufactured or reprocessed, assembled and packaged;

— the control of equipment and processes;

— the control of personnel and their hygiene;

— the manner and materials in which the product is packaged;

— the conditions under which product is stored.

The type of contamination on a product to be sterilized varies and this impacts upon the effectiveness of a sterilization process. Products that have been used in a health care setting and are being presented for resterilization in accordance with the manufacturer's instructions (see ISO 17664) are a special case. There is the potential for such products to possess a wide range of contaminating microorganisms and residual inorganic and/or organic contamination in spite of the application of a cleaning process. Hence, it is important to pay particular attention to the validation and control of the cleaning and disinfection processes used during reprocessing. Mixed product loads are common in health care facilities with throughput volumes dictated by historical and predicted demand for sterile product.

© ISO 2014 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS EN ISO 11135:2014+A1:2019

The requirements are the normative parts of ISO 11135 with which compliance is claimed. The guidance given in the informative annexes is not normative and is not provided as a checklist for auditors. The guidance in Annex D provides explanations and methods that are regarded as being suitable means for complying with the requirements for industry and health care facilities.

The guidance, in Annex D, is intended for people who have a basic knowledge of the principles of EO sterilization. Methods other than those given in the guidance can be used if they are effective in achieving compliance with the requirements of ISO 11135.

The development, validation and routine control of a sterilization process comprises a number of discrete but interrelated activities; e.g. calibration, maintenance, product definition, process definition, installation qualification, operational qualification and performance qualification. While the activities required by ISO 11135 have been grouped together and are presented in a particular order, ISO 11135 does not require that the activities be performed in the order in which they are presented. The activities required are not necessarily sequential, as the programme of development and validation may be iterative. It is possible that performing these different activities will involve a number of separate individuals and/or organizations, each of whom undertakes one or more of these activities. This International Standard does not specify the particular individuals or organizations to carry out the activities.

It is important that patient safety be addressed by minimizing exposure to EO and its by-products during normal product use. ISO 10993-7 specifies limits for EO and ethylene chlorohydrin (ECH); however, no exposure limits are set for ethylene glycol (EG) because risk assessment indicates that when EO residues are controlled, it is unlikely that biologically significant residues of EG would be present.

© ISO 2014 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS EN ISO 11135:2014+A1:2019

This page deliberately left blank

Documents
Document Sharing Hub

INTERNATIONAL STANDARD **ISO 11135:2014+A1:2018**

Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices

1 Scope

1.1 Inclusions

This International Standard specifies requirements for the development, validation and routine control of an ethylene oxide sterilization process for medical devices in both the industrial and health care facility settings, and it acknowledges the similarities and differences between the two applications.

NOTE 1 Among the similarities are the common need for quality systems, staff training, and proper safety measures. The major differences relate to the unique physical and organizational conditions in health care facilities, and to the initial condition of reusable medical devices being presented for sterilization.

NOTE 2 Health care facilities differ from medical device manufacturers in the physical design of processing areas, in the equipment used, and in the availability of personnel with adequate levels of training and experience. The primary function of the health care facility is to provide patient care; medical device reprocessing is just one of a myriad of activities that are performed to support that function.

NOTE 3 In terms of the initial condition of medical devices, medical device manufacturers generally sterilize large numbers of similar medical devices that have been produced from virgin material. Health care facilities, on the other hand, must handle and process both new medical devices and reusable medical devices of different descriptions and with varying levels of bioburden. They are therefore faced with the additional challenges of cleaning, evaluating, preparing and packaging a medical device prior to sterilization. In this International Standard, alternative approaches and guidance specific to health care facilities are identified as such.

NOTE 4 EO gas and its mixtures are effective sterilants that are primarily used for heat- and/or moisture-sensitive medical devices that cannot be moist heat sterilized.

NOTE 5 Although the scope of this International Standard is limited to medical devices, it specifies requirements and provides guidance that can be applicable to other health care products.

1.2 Exclusions

1.2.1 This International Standard does not specify requirements for the development, validation and routine control of a process for inactivating the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents.

NOTE See ISO 22442-1, ISO 22442-2 and ISO 22442-3.

1.2.2 This International Standard does not detail a specified requirement for designating a medical device as sterile.

NOTE Attention is drawn to national or regional requirements for designating medical devices as “sterile”. See for example EN 556-1 or ANSI/AAMI ST67.

1.2.3 This International Standard does not specify a quality management system for the control of all stages of production of medical devices.

© ISO 2014 – All rights reserved

Documents
Document Sharing Hub

Full document details: BS EN ISO 11135:2014+A1:2019

NOTE The effective implementation of defined and documented procedures is necessary for the development, validation and routine control of a sterilization process for medical devices. Such procedures are commonly considered to be elements of a quality management system. It is not a requirement of this International Standard to have a full quality management system during manufacture or reprocessing. The necessary elements are normatively referenced at appropriate places in the text (see, in particular, Clause 4). Attention is drawn to the standards for quality management systems (see ISO 13485) that control all stages of production or reprocessing of medical devices. National and/or regional regulations for the provision of medical devices might require the implementation of a full quality management system and the assessment of that system by a third party.

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

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

NOTE 2 EO is toxic, flammable and explosive. Attention is drawn to the possible existence in some countries of regulations giving safety requirements for handling EO and for premises in which it is used.

1.2.5 This International Standard does not cover sterilization by injecting EO or mixtures containing EO directly into packages or a flexible chamber.

NOTE See ISO 14937 for these types of EO processes.

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

NOTE 1 For further information see ISO 10993-7.

NOTE 2 Attention is drawn to the possible existence of national or regional regulations specifying limits for the level of EO residues present on or in medical devices.

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.

ISO 10012, *Measurement management systems — Requirements for measurement processes and measuring equipment*

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

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

〚A1〛ISO 11138-2:2006〚A1〛, *Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes*

〚A1〛ISO 11138-7: —[1)], *Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results*〚A1〛

ISO 11140-1, *Sterilization of health care products — Chemical indicators — Part 1: General requirements*

ISO 11737-1, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

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*

1) Under preparation.

© ISO 2014 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS EN ISO 11135:2014+A1:2019

ISO 13485:2003/Cor 1:2009, *Medical devices — Quality management systems — Requirements for regulatory purposes — Technical Corrigendum 1*

3 Terms and definitions

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

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

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

3.2
aeration area
either a chamber or a room in which aeration occurs

3.3
bioburden
population of viable microorganisms on or in product and/or sterile barrier system

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

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

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

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

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

3.6
chemical indicator
test system that reveals a change in one or more pre-defined process variables based on a chemical or physical change resulting from exposure to a process

[SOURCE: ISO/TS 11139:2006, definition 2.6]

3.7
conditioning
treatment of product within the sterilization cycle, but prior to ethylene oxide admission, to attain a predetermined temperature and relative humidity

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

Note 2 to entry: See 3.27, preconditioning.

© ISO 2014 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS EN ISO 11135:2014+A1:2019

3.8
***D* value**
D_{10} value
time or dose required to achieve inactivation of 90 % of a population of the test microorganism under stated conditions

[SOURCE: ISO/TS 11139:2006, definition 2.11]

Note 1 to entry: For the purposes of this International Standard, the *D* value is the exposure time required to achieve 90 % inactivation of the population of the test organism.

3.9
development
act of elaborating a specification

[SOURCE: ISO/TS 11139:2006, definition 2.13]

3.10
dew point
The temperature at which the saturation water vapour pressure is equal to the partial pressure of the water vapour in the atmosphere

Note 1 to entry: Any cooling of the atmosphere below the dew point would produce water condensation.

3.11
establish
determine by theoretical evaluation and confirm by experimentation

[SOURCE: ISO/TS 11139:2006, definition 2.17]

3.12
ethylene oxide (EO) injection time
duration of the stage beginning with the first introduction of the EO (mixture) into the chamber to the completion of that injection

3.13
exposure time
period for which the process parameters are maintained within their specified tolerances

[SOURCE: ISO/TS 11139:2006, definition 2.18]

Note 1 to entry: For the purpose of calculation of cycle lethality, it is the period of sterilization between the end of EO injection and the beginning of EO removal.

3.14
fault
one or more of the process parameters lying outside of its/their specified tolerance(s)

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

3.15
flushing
procedure by which the ethylene oxide is removed from the load and chamber by either multiple alternate admissions of filtered air, inert gas or steam and evacuations of the chamber or continuous passage of filtered air, inert gas or steam through the load and chamber

3.16
fractional cycle
a cycle in which the exposure time to EO gas is reduced compared to that specified in the sterilization process

© ISO 2014 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS EN ISO 11135:2014+A1:2019

3.17
half cycle
a cycle in which the exposure time to EO gas is reduced by 50 % compared to that specified in the sterilization process

3.18
health care facility
HCF
governmental and private organizations and institutions devoted to the promotion and maintenance of health, and the prevention and treatment of diseases and injuries

EXAMPLE A health care facility can be a hospital, nursing home, extended care facility, free-standing surgical centre, clinic, medical office, or dental office.

3.19
health care product
medical device(s), including *in vitro* diagnostic medical device(s), or medicinal product(s), including biopharmaceutical(s)

[SOURCE: ISO/TS 11139:2006, definition 2.20]

3.20
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, definition 2.22]

3.21
medical device
any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material 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 or modification or support of the anatomy or of a physiological process,

— 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 principal 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: ISO 13485:2003, definition 3.7]

3.22
microorganism
entity of microscopic size, encompassing bacteria, fungi, protozoa and viruses

Note 1 to entry: A specific standard might not require demonstration of the effectiveness of the sterilization process in inactivating all types of microorganisms, identified in the definition above, for validation and/or routine control of the sterilization process.

[SOURCE: ISO/TS 11139:2006, definition 2.26]

© ISO 2014 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS EN ISO 11135:2014+A1:2019

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, definition 2.27]

3.24
overkill approach
approach using sterilization process that delivers a minimum of 12 Spore Log Reduction (SLR) to a biological indicator having a resistance equal to or greater than the product bioburden

3.25
parametric release
declaration that product is sterile, based on records demonstrating that the process parameters were delivered within specified tolerances

[SOURCE: ISO/TS 11139:2006, definition 2.29]

Note 1 to entry: This method of process release does not include the use of biological indicators.

3.26
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, definition 2.30]

3.27
preconditioning
treatment of product, prior to the sterilization cycle, in a room or chamber to attain specified conditions for temperature and relative humidity

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

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

Note 1 to entry: For the purpose of this International Standard, a PCD can be product, simulated product or other device that is inoculated directly or indirectly. See 7.1.6 and D.7.1.6.

Note 2 to entry: In this International Standard, a distinction is made between an internal PCD and an external PCD. An internal PCD is used to demonstrate that the required product SAL is achieved. A PCD located within the confines of the product or product shipper case is an internal PCD, whereas a PCD located between shipper cases or on the exterior surfaces of the load is an external PCD. An external PCD is an item designed to be used for microbiological monitoring of routine production cycles.

3.29
process parameter
specified value for a process variable

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

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

© ISO 2014 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS EN ISO 11135:2014+A1:2019

3.30
process variable
condition within a sterilization process, changes in which alter microbicidal effectiveness

EXAMPLE Time, temperature, pressure, concentration, humidity, wavelength.

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

3.31
processing category
collection of different product or product families that can be sterilized together

Note 1 to entry: All products within the category have been determined to present an equal or lesser challenge to the sterilization process than the process challenge device for that group.

3.32
product
result of a process

[SOURCE: ISO 9000:2005, definition 3.4.2]

Note 1 to entry: For the purposes of sterilization standards, product is tangible and can be raw material(s), intermediate(s), sub-assembly(ies) and health care products.

3.33
product family
group of product possessing characteristics that allow them to be sterilized using defined process conditions

3.34
product load volume
defined space within the usable chamber volume occupied by product

3.35
recognized culture collection
depository authority under the Budapest Treaty on *The International Recognition of the Deposit of Microorganisms for the Purposes of Patent and Regulation*

[SOURCE: ISO/TS 11139:2006, definition 2.38]

3.36
reference microorganism
microbial strain obtained from a recognized culture collection

[SOURCE: ISO/TS 11139:2006, definition 2.39]

3.37
requalification
repetition of part of validation for the purpose of confirming the continued acceptability of a specified process

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

3.38
reusable medical device
medical device designated or intended by the manufacturer as suitable for reprocessing and re-use

Note 1 to entry: This is not a medical device that is designated or intended by the manufacturer for single use only.

© ISO 2014 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS EN ISO 11135:2014+A1:2019

3.39
services
supplies from an external source, needed for the correct function of equipment

EXAMPLE Electricity, water, compressed air, drainage.

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

3.40
single use medical device
medical device designated or intended by the manufacturer for one-time use only

3.41
specify
stipulate in detail within an approved document

[SOURCE: ISO/TS 11139:2006, definition 2.42]

3.42
Spore-log-reduction
SLR
log of initial spore population, N_0, minus the log of the final population, N_u

[SOURCE: ISO 14161:2009, definition 3.19]

Note 1 to entry: Describing the reduction in the number of spores on a biological indicator or inoculated item produced by exposure to specified conditions.

For Direct Enumeration:

$SLR = \log N_0 - \log N_u$

where

N_0 is the initial population;

N_u is the final population.

For Fraction Negative:

$SLR = \log N_0 - \log [\ln (q/n)]$

where

N_0 is the initial population;

q is the number of replicate samples tested;

n is the number of samples negative for growth.

If there are no survivors, the true SLR cannot be calculated. The SLR can be reported as "greater than" $\log N_0$ if one surviving organism is used.

3.43
sterile
free from viable microorganisms

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

© ISO 2014 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS EN ISO 11135:2014+A1:2019

3.44
sterile barrier system
minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use

[SOURCE: ISO/TS 11139:2006, definition 2.44]

3.45
sterility
state of being free from viable microorganisms

Note 1 to entry: In practice, no such absolute statement regarding the absence of microorganisms can be proven.

Note 2 to entry: See 3.47, sterilization.

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

3.46
sterility assurance level
SAL
probability of a single viable microorganism occurring on an item after sterilization

Note 1 to entry: The term SAL takes a quantitative value, generally 10^{-6} or 10^{-3}. When applying this quantitative value to assurance of sterility, an SAL of 10^{-6} has a lower value but provides a greater assurance of sterility than an SAL of 10^{-3}.

[SOURCE: ISO/TS 11139:2006, definition 2.46]

3.47
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.

Note 2 to entry: See 3.46, sterility assurance level.

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

3.48
sterilization cycle
treatment in a sealed chamber, which includes air removal, conditioning (if used), injection of ethylene oxide, inert gas (if used), exposure to ethylene oxide, removal of ethylene oxide and flushing (if used), and air/inert gas admission

3.49
sterilization load
product to be, or that has been, sterilized together using a given sterilization process

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

3.50
sterilization process
series of actions or operations needed to achieve the specified requirements for sterility

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

Note 1 to entry: This series of actions or operations includes preconditioning (if necessary), exposure to the ethylene oxide under defined conditions and any necessary post-treatment required for the removal of ethylene oxide and its by-products. It does not include any cleaning, disinfection or packaging operations that precede the sterilization process.

© ISO 2014 – All rights reserved

AVA Documents
Document Sharing Hub
Full document details: BS EN ISO 11135:2014+A1:2019