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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

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 It supersedes BS EN ISO 11135:2014, which is withdrawn.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.

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

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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

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11135:2014 +A1

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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.

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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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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.

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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.

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.

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.

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.

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.

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.

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.

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.