BSI Standards Publication

Sterilization of health care products — Radiation

Part 1: 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 11137-1:2026. It is identical to ISO 11137-1:2025. It supersedes BS EN ISO 11137-1:2015+A2:2019, which is withdrawn.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 committee manager.

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This publication has been prepared under a mandate given to the European Standards Organizations by the European Commission and the European Free Trade Association. It is intended to support requirements of the EU legislation detailed in the European Foreword. A European Annex, usually Annex ZA or ZZ, describes how this publication relates to that EU legislation.

For the Great Britain market (England, Scotland and Wales), if UK Government has designated this publication for conformity with UKCA marking (or similar) legislation, it may contain an additional National Annex. Where such a National Annex exists, it shows the correlation between this publication and the relevant UK legislation. If there is no National Annex of this kind, the relevant Annex ZA or ZZ in the body of the European text will indicate the relationship to UK regulation applicable in Great Britain. References to EU legislation may need to be read in accordance with the UK designation and the applicable UK law. Further information on designated standards can be found at www.bsigroup.com/standardsandregulation.

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Published by BSI Standards Limited 2026

ISBN 978 0 539 15412 2

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 30 June 2026.

Amendments/corrigenda issued since publication

Date	Text affected

EUROPEAN STANDARD **EN ISO 11137-1**

NORME EUROPÉENNE

EUROPÄISCHE NORM

June 2026

ICS 11.080.01

Supersedes EN ISO 11137-1:2015

English Version

Sterilization of health care products - Radiation - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2025)

Stérilisation des produits de santé - Irradiation - Partie 1: Exigences relatives à la mise au point, à la validation et au contrôle de routine d'un procédé de stérilisation pour les dispositifs médicaux (ISO 11137-1:2025)

Sterilisation von Produkten für die Gesundheitsfürsorge - Strahlen - Teil 1: Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (ISO 11137-1:2025)

This European Standard was approved by CEN on 12 March 2025.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 11137-1:2026 E

European foreword

This document (EN ISO 11137-1:2026) 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 December 2026, and conflicting national standards shall be withdrawn at the latest by December 2026.

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 11137-1:2015.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA or ZB, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 11137-1:2025 has been approved by CEN as EN ISO 11137-1:2026 without any modification.

Annex ZA
(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 M/575 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] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

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 ZA.1 and application of the edition of the normatively referenced standards as given in Table ZA.2 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.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences are indicated in Table ZA.3. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European regulation for medical devices (EU) 2017/745).

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 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 Regulation (EU) 2017/745 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
11.3	5,6,8,9,10,11	This standard provides requirements for the development, validation and routine control of a sterilization process using radiation for medical devices, 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 General Safety and Performance Requirement is addressed only with regard to devices for which treatment by irradiation 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 radiation are not covered.
11.4 first sentence only	5,6,8,9,10,11	This standard provides requirements for the development, validation and routine control of a sterilization process using radiation for medical devices, 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 irradiation 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 by radiation are not covered. Evidence that the integrity of the packaging is maintained to the point of use is not covered.
11.5	5,6,8,9,10,11	This standard provides requirements for the development, validation and routine control of a sterilization process using radiation for medical devices, 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 irradiation is appropriate. This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Packaging for maintenance of sterility is not covered. Aspects of manufacture other than those related to attainment of sterility by radiation are not covered.

Table ZA.2 — Normative references from Clause 2 of this document and their corresponding European publications

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO 11137-2:2013	ISO 11137-2:2013 ISO 11137-2:2013/Amd1:2022	Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose	EN ISO 11137-2:2015 EN ISO 11137-2:2015/A1:2023
ISO 13004	ISO 13004:2022	Sterilization of heath care products — Radiation — Substantiation of selected sterilization dose: Method VDmaxSD	EN ISO 13004:2023
ISO 11737-1	ISO 11737-1:2018 ISO 11737-1:2018/Amd1:2021	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018 EN ISO 11737-1:2018/A1:2021
ISO 11737-2	ISO 11737-2:2019	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	EN ISO 11737-2:2020
ISO/ASTM 52628	ISO/ASTM 52628:2020	Standard Practice for Dosimetry in Radiation Processing	N/A

The documents listed in the Column 1 of Table ZA.2, in whole or in part, are normatively referenced in this document, i.e. are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of Table ZA.2.

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.

Table ZA.3 — Definitions in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745

Term	Definition in Clause 3 of this document	Definition in Regulation (EU) 2017/745
Corrective Action	action to eliminate the cause of a nonconformity and to prevent recurrence Note 1 to entry: There can be more than one cause for a nonconformity. Note 2 to entry: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence. [SOURCE: ISO 9000:2015, 3.12.2, modified — Note 3 to entry has been deleted.]	'corrective action' means action taken to eliminate the cause of a potential or actual non-conformity or other undesirable situation;
Medical Device	instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, or software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: - diagnosis, prevention, monitoring, treatment or alleviation of disease; - diagnosis, monitoring, treatment, alleviation of or compensation for an injury; - investigation, replacement, modification, or support of the anatomy or of a physiological process; - supporting or sustaining life; - control of conception; - disinfection of medical devices; - providing information by means of in vitro examination of specimens derived from the human	'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: - diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, - diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, - investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, - providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the

	body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include: - items specifically intended for cleaning or sterilization of medical devices; - pouches, reel goods, sterilization wrap, and reusable containers for packaging of medical devices for sterilization; - disinfection substances; - aids for persons with disabilities; - devices incorporating animal and/or human tissues; - devices for in vitro fertilization or assisted reproduction technologies. [SOURCE: ISO 13485:2016, 3.11, modified — The first two list items in Note 1 to entry have been added.]	human body, but which may be assisted in its function by such means. The following products shall also be deemed to be medical devices: - devices for the control or support of conception; - products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

Annex ZB
(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 M/575 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] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, performance studies, clinical evidence or post-market performance follow-up.

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 ZB.1 and application of the edition of the normatively referenced standards as given in Table ZA.2 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.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/746, the differences are indicated in Table ZB.2. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/746, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the In vitro Diagnostic Regulation (EU) 2017/746).

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 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 Regulation (EU) 2017/746 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, performance studies, clinical evidence or post-market performance follow-up.

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
11.2	5,6,8,9,10,11	This standard provides requirements for the development, validation and routine control of a sterilization process using radiation for medical devices, including requirements that the sterilized medical device is safe and performs as intended after sterilization. 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 General Safety and Performance Requirement is addressed only with regard to devices for which treatment by irradiation 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 radiation are not covered.
11.3	5,6,8,9,10,11	This standard provides requirements for the development, validation and routine control of a sterilization process using radiation for medical devices, 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 irradiation is appropriate. This relevant General Safety and Performance Requirement is only partly addressed in this European

		Standard. Packaging for maintenance of sterility is not covered. Aspects of manufacture other than those related to attainment of sterility by radiation 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.

Table ZB.2 — Definitions in this standard differs from a definition of the same term set out in Regulation (EU) 2017/746

Term	Definition in Clause 3 of this document	Definition in Regulation (EU) 2017/746
Corrective Action	action to eliminate the cause of a nonconformity and to prevent recurrence Note 1 to entry: There can be more than one cause for a nonconformity. Note 2 to entry: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence. [SOURCE: ISO 9000:2015, 3.12.2, modified — Note 3 to entry has been deleted.]	'corrective action' means action taken to eliminate the cause of a potential or actual non-conformity or other undesirable situation;
Medical Device	instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, or software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: - diagnosis, prevention, monitoring, treatment or alleviation of disease; - diagnosis, monitoring, treatment, alleviation of or compensation for an injury; - investigation, replacement, modification, or support of the anatomy or of a physiological process; - supporting or sustaining life;	'medical device' means 'medical device' as defined in point (1) of Article 2 of Regulation (EU) 2017/745;

	- control of conception; - disinfection of medical devices; - providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include: - items specifically intended for cleaning or sterilization of medical devices; - pouches, reel goods, sterilization wrap, and reusable containers for packaging of medical devices for sterilization; - disinfection substances; - aids for persons with disabilities; - devices incorporating animal and/or human tissues; - devices for in vitro fertilization or assisted reproduction technologies. [SOURCE: ISO 13485:2016, 3.11, modified — The first two list items in Note 1 to entry have been added.]	