ILNAS

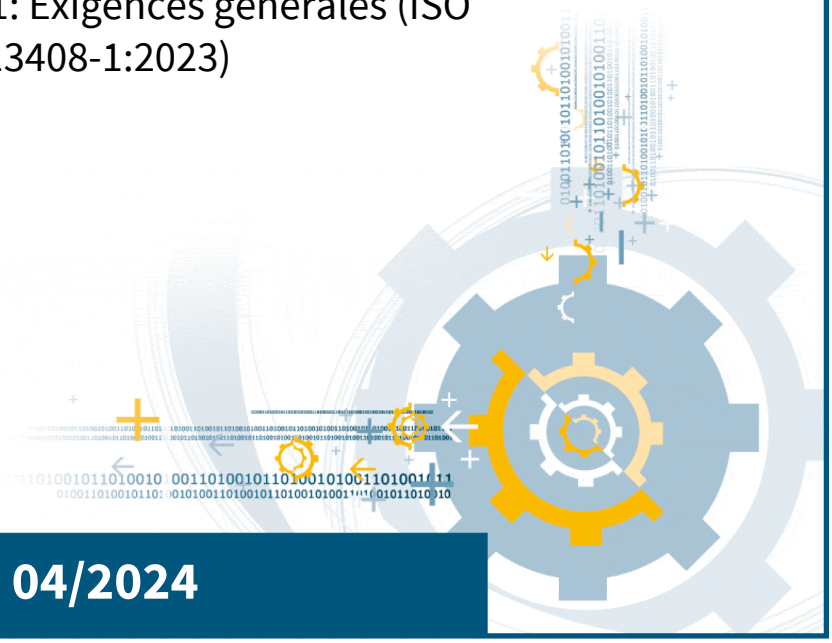
Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN ISO 13408-1:2024

Aseptic processing of health care products - Part 1: General requirements (ISO 13408-1:2023)

Aseptische Herstellung von Produkten für die Gesundheitsfürsorge - Teil 1: Allgemeine Anforderungen (ISO 13408-1:2023)

Traitement aseptique des produits de santé - Partie 1: Exigences générales (ISO 13408-1:2023)



04/2024

National Foreword

This European Standard EN ISO 13408-1:2024 was adopted as Luxembourgish Standard ILNAS-EN ISO 13408-1:2024.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 13408-1

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ICS 11.080.01

Supersedes EN ISO 13408-1:2015

English Version

Aseptic processing of health care products - Part 1: General requirements (ISO 13408-1:2023)

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This European Standard was approved by CEN on 2 July 2023.

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, 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 United Kingdom.

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

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European foreword

This document (EN ISO 13408-1:2024) 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 October 2024, and conflicting national standards shall be withdrawn at the latest by October 2024.

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 13408-1:2015.

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 and 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 13408-1:2023 has been approved by CEN as EN ISO 13408-1:2024 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 shall be indicated in this Annex Z. 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	4,5,6,7,8,9	This standard provides general requirements for processes, programs and procedures for development, validation and routine control of aseptic processing. This General Safety and Performance Requirement is addressed only with regard to devices for which use of aseptic processing is appropriate. This General Safety and Performance Requirement is only partly addressed in this European Standard. Design and packaging for maintenance of sterility are not covered. Aspects of manufacture other than those related to maintenance of a specific microbial state by aseptic processing are not covered.
11.4 first sentence only	4,5,6,7,8,9	This standard provides general requirements for processes, programs and procedures for development, validation and routine control of aseptic processing. This General Safety and Performance Requirement is addressed only with regard to devices for which use of aseptic processing is appropriate. This General Safety and Performance Requirement is only partly addressed in this European Standard. Design and packaging for maintenance of sterility are not covered. Evidence that the integrity of the packaging is maintained to the point of use is not covered. Aspects of manufacture other than those related to maintenance of sterility during aseptic processing are not covered. Transport and storage conditions are not covered.
11.5	4,5,6,7,8,9	This standard provides general requirements for processes, programs and procedures for development, validation and routine control of aseptic processing. This General Safety and Performance Requirement is addressed only with regard

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
		to devices for which use of aseptic processing is appropriate. This General Safety and Performance Requirement is only partly addressed in this European Standard. Design and packaging for maintenance of sterility are not covered. Aspects of manufacture other than those related to maintenance of sterility during aseptic processing are not covered.

Table ZA.2 — Applicable Standards to confer presumption of conformity as described in this Annex ZA

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO 13408-2	ISO 13408-2:2018	Aseptic processing of health care products — Part 2: Sterilizing filtration	EN ISO 13408-2:2018
ISO 13408-6	ISO 13408-6:2021	Aseptic processing of health care products — Part 6: Isolator systems	EN ISO 13408-6:2021
ISO 14644-1:2015	ISO 14644-1:2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
ISO 14644-2	ISO 14644-2:2015	Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	EN ISO 14644-2:2015
ISO 14664-4	ISO 14664-4:2001	Cleanrooms and associated controlled environments — Part 4: Design, construction and start-up	EN ISO 14664-4:2001
ISO 14644-7	ISO 14644-7:2004	Cleanrooms and associated controlled environments — Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)	EN ISO 14644-7:2004

The documents listed in the Column 1 of Table ZA.2, in whole or in part, are normatively referenced in this document and 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.