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Pakkematerialer til terminalsteriliseret medicinsk udstyr – Del 1: Krav til materialer, sterilbarrieresystemer og pakkesystemer – Tillæg 1: Anvendelse af risikoledelse

Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems – Amendment 1: Application of risk management (ISO 11607-1:2019/Amd 1:2023)

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IDT med: EN ISO 11607-1:2020/A1:2023

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Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems - Amendment 1: Application of risk management (ISO 11607-1:2019/Amd 1:2023)

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière stérile et aux systèmes d'emballage - Amendement 1: Application de la gestion des risques (ISO 11607-1:2019/Amd 1:2023)

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 1: Anforderungen an Materialien, Sterilbarrieresysteme und Verpackungssysteme - Änderung 1 (ISO 11607-1:2019/Amd 1:2023)

This amendment A1 modifies the European Standard EN ISO 11607-1:2020; it was approved by CEN on 12 September 2023.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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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Ref. No. EN ISO 11607-1:2020/A1:2023 E

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European foreword

This document (EN ISO 11607-1:2020/A1:2023) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 102 “Sterilizers and associated equipment for processing of medical devices” the secretariat of which is held by DIN.

This Amendment to the European Standard EN ISO 11607-1:2020 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2024, and conflicting national standards shall be withdrawn at the latest by April 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 has been prepared under a Standardization Request given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s) / Regulation(s).

For relationship with EU Directive(s) / Regulation(s), see informative Annex ZA and Annex ZB, which are integral parts 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 11607-1:2019/Amd 1:2023 has been approved by CEN as EN ISO 11607-1:2020/A1:2023 without any modification.

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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 harmonised standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall indicated in the 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 document 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.

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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
1	6.1.1 (including Annex F), 6.1.2, 6.1.3, 6.1.4, 6.1.5, 6.1.6, 6.1.8, 6.2.1, 6.2.2, 6.2.3, 6.2.4 (if applicable), 6.2.5	Partially covered: Covered for the packaging of sterile devices making sure that the sterile packaging is safe for its intended purpose by applying risk management considering the generally acknowledged state of the art. Does not cover the weighing against the benefits to the patient as this needs to consider the specific intended purpose of the packaged device and cannot be covered by sterile packaging alone.
3	4.2, Annex F	Partially covered: Covered for sterile packaging as the focus of EN ISO 11607-1:2020/A1:2023 is to provide a framework for applying risk management to SBSs. Does not cover the benefits-risk ratio to the patient as this needs to consider the specific intended purpose of the packaged medical device and cannot be covered by sterile packaging alone. Evaluation of production and post market surveillance information under GSPR 3 (e) against overall risk and benefit risk-ratio is not covered, not part of the scope of EN ISO 11607-1: 2020/A1:2023, GSPR 3 (f) only covered for production phase and if post-production information is available, to determine if risks are controlled appropriately.
4	5.1.10, 6, 7.5, 8, 10, Annex F.7	Partially covered: Applying this principle for maintenance of sterility through rigorous performance and stability testing and by qualification of materials, design with systematic risk reduction, process development to minimize risk. Addresses also instructions for use and label as relevant for integrity inspections, aseptic presentation and for reusable materials and/or reusable preformed sterile barrier systems.
5	6.1.2, 6.2.3, 7	Partially covered: GSPR 5 (a) is only addressed partially, ergonomic features not directly addressed GSPR 5 (b) is addressed as design factors include user requirements and environment for packaging, packaging usability evaluation is a test

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General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
		that will address ergonomic features for aseptic presentation (Clause 7).
6	6.1.6, 8	Partially covered for sterile packaging and maintenance of sterility, shelf-life aging studies, all from a packaging point of view.
7	6.1.6, 8	Partially covered for sterile packaging and maintenance of sterility.
10		Not covered.
11.1	4.2, Annex F, 6.1.1, 6.1.2, 6.1.3 6.1.6, 6.1.8, 7	Partially covered: GSPR 11.1 (b) and (d) are covered only in respect of the function of the sterile barrier system(s) to protect the sterility of the medical device from the point of sterilisation to the point of use, and to allow for aseptic presentation. The standard includes a way to evaluate the packaging design in terms of usability to provide supportive evidence for GSPR 11.1 (b) covering the aspect of aseptic presentation. The standard includes a packaging performance and stability testing approach for sterile barrier system integrity as supportive evidence for GSPR 11.1 (d). GSPR 11.1 (a), and 11.1 (c) are not covered. The standard does not address infection risks related to 3rd parties or other persons.
11.2		Applicable only for reusable sterilization containers and reusable materials. No presumption of conformity.
11.4	4.2, 4.4, 5.2, 6.1.3, 6.1.4, 6.1.6, 6.1.9, 8.1, 8.2.1, 8.2.2, 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6	Partially covered: GSPR 11.4 is covered only in respect of the function of sterile barrier system(s) to protect the sterility of the device from the point of sterilisation to the point of use and to allow for aseptic presentation. In this respect damage to the "packaging which is intended to maintain their sterile condition" is taken to mean damage to or loss of integrity of the sterile barrier system only. Regarding the aspects of "clearly evident integrity of the packaging", this document does not include criteria.
11.5	4.2, 4.4, 5.3.1, 5.3.2, 5.3.3, 6.1.2, 6.1.3,	Partially covered: GSPR 11.5 is covered only in respect of the compatibility between the

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General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
	6.1.5, 6.1.6, 6.1.9, 8.1, 8.2.1, 8.2.2, 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6, 9.1	packaging and the selected sterilisation processes and packaging system validation consisting of usability evaluation, performance testing and sterile barrier system stability testing as well as validation of forming, sealing and assembling processes following EN ISO 11607-2:2020/A1:2023.
11.6		Not covered.
11.7		Not covered.
11.8		Not covered.
13		Not covered.
22.1	7	Partially covered: No specific requirements for lay persons. User and environment of use are factors to include into the design and the standard includes a way to evaluate the packaging design in terms of usability to provide supportive evidence for covering the aspect of aseptic presentation.
22.2	7	Partially covered: No specific requirements for lay persons, user and environment of use are factors to include into the design and the standard includes a way to evaluate the packaging design in terms of usability to provide supportive evidence for covering the aspect of aseptic presentation. No requirements for risk from unintended cuts and pricks such as needle stick injuries.
23.3		Not covered. EN ISO 11607-1:2020/A1:2023 covers GSPR 23.3 (a), but refers to EN ISO 15223-1 for symbols.
23.4		Not covered.

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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 5636-5	ISO 5636-5:2013	Paper and board — Determination of air permeance and air resistance (medium range) — Part 5: Gurley method	None For applicable standard edition see Column 2
ISO 11607-2	ISO 11607-2:2019 ISO 11607-2:2019/Amd1:2023	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2:2020 EN ISO 11607-2:2020/A11:2022 EN ISO 11607-2:2020/A1:2023

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.

INTERNATIONAL ISO

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AMENDMENT 1
2023-09

Packaging for terminally sterilized medical devices —

Part 1: Requirements for materials, sterile barrier systems and packaging systems

AMENDMENT 1: Application of risk management

Emballages des dispositifs médicaux stérilisés au stade terminal —

Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière stérile et aux systèmes d'emballage

AMENDEMENT 1: Application de la gestion des risques

Reference number
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Foreword

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

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

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers for medical purposes,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 11607 series can be found on the ISO website.

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Packaging for terminally sterilized medical devices —

Part 1: Requirements for materials, sterile barrier systems and packaging systems

AMENDMENT 1: Application of risk management

Clause 1, Scope

Delete the following text:

> It is applicable to industry, to health care facilities, and to wherever medical devices are placed in sterile barrier systems and sterilized.

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