Pakkematerialer til terminalsteriliseret medicinsk udstyr – Del 2: Valideringskrav til formgivnings-, forseglings- og samleprocesser

Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes – Amendment 1: Application of risk management (ISO 11607-2:2019/Amd 1:2023)

DANSK STANDARD
Danish Standards Association

Göteborg Plads 1
DK-2150 Nordhavn

Tel: +45 39 96 61 01
dansk.standard@ds.dk
www.ds.dk

DS projekt: M364495
ICS: 11.080.30

Første del af denne publikations betegnelse er:
DS/EN ISO, hvilket betyder, at det er en international standard, der har status både som europæisk og dansk standard.

Denne publikations overensstemmelse er:
IDT med: ISO 11607-2:2019/Amd 1:2023
IDT med: EN ISO 11607-2:2020/A1:2023

DS-publikationen er på engelsk.

EUROPÄISCHE NORM

October 2023

ICS 11.080.30

English Version

Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes - Amendment 1: Application of risk management (ISO 11607-2:2019/Amd 1:2023)

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 2: Exigences de validation pour les procédés de formage, scellage et assemblage - Amendement 1: Application de la gestion des risques (ISO 11607-2:2019/Amd 1:2023)

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 2: Validierungsanforderungen an Prozesse der Formgebung, Siegelung und des Zusammenstellens - Änderung 1 (ISO 11607-2:2019/Amd 1:2023)

This amendment A1 modifies the European Standard EN ISO 11607-2:2020; 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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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 11607-2:2020/A1:2023 E

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European foreword

This document (EN ISO 11607-2:2020/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 11607-2:2020 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 11607-2:2019/Amd 1:2023 has been approved by CEN as EN ISO 11607-2:2020/A1:2023 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 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.

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	4.2, Annex B 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 6.1, 6.2, 6.3, if applicable 7, 8	Partially covered: Covers this GSPR for the packaging of sterile medical devices through process development, validation of the sealing and assembly process, production control by applying risk management to all these phases. Does not cover the weighing against the benefits to the patient as this needs to consider the specific intended purpose of the medical device and cannot be covered by sterile packaging alone.
3	4.2, Annex B	Partially covered: Covered for sterile packaging by providing a framework for applying risk management to sterile packaging over the phases of design, process development, validation and production. Does not cover the benefits-risk ratio to the patient as this needs to consider the specific intended purpose of the 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 11607-2:2020/A1:2023. GSPR 3 (f) only covered (see B.2) for production phase and if post-production information is available, to determine if risks are controlled appropriately.
4	4.2, Annex B	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.
5		Not covered: Applicable only to EN ISO 11607-1:2020/A1:2023.
6		Not covered: Applicable only to EN ISO 11607-1:2020/A1:2023.

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
7	4.2, Annex B, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 6.1, 6.2, 6.3, if applicable: 7, 8	Partially covered for sterile packaging by validating the forming, assembly and sealing process.
10		Not covered.
11.1	4.2, Annex B 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 6.1, 6.2, 6.3, if applicable: 7, 8	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 device from the point of sterilisation to the point of use and to allow for aseptic presentation and only if the requirements of EN ISO 11607-1:2020/A1:2023 are met as well. GSPR 11.1 (a), and 11.1 (c) are not covered. Clause 5 addresses the requirements of packaging processes and the way to validate. Subclause 5.7 addresses management of changes and revalidations to maintain the process in the state of control. SBS assembly requirements are listed in Clause 6. Specifics for reusable SBS are covered in Clause 7. Specifics for sterile fluid-path SBS are covered in Clause 8.
11.2		Not covered: Applicable only to reusable sterilization containers and reusable materials (EN ISO 11607-1:2020/A1:2023). No presumption of conformity.

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
11.4	4.2, Annex B, 4.3, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7 6.1, 6.2, 6.3, if applicable: 8	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 but only if the requirements of EN ISO 11607-1:2020/A1:2023 are met as well (requirements for materials, sterile barrier systems and packaging systems). 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 includes considerations for seals and closure quality properties as supportive requirements for compliance. Clause 5 addresses the requirements of packaging processes and the way to validate. Subclause 5.7 addresses management of changes and revalidations to maintain the process in the state of control. SBS assembly requirements are listed in clauses 6. Specifics for sterile fluid-path SBS are covered in Clause 8.
11.5	4.2, Annex B, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7 6.1, 6.2, 6.3, If applicable: 8	Partially covered: GSPR 11.5 is covered only in respect of the validation of forming, sealing and assembling processes for packaging, assuming that the requirements of EN ISO 11607-1:2020/A1:2023 are met as well (requirements for materials, sterile barrier systems and packaging systems which includes compatibility between the packaging and the selected sterilisation processes, packaging system performance testing and sterile barrier system stability testing). Clause 5 addresses the requirements of packaging processes and the way to validate. Subclause 5.7 addresses management of changes and revalidations to maintain the process in the state of control. SBS assembly requirements are listed in clauses 6. Specifics for sterile fluid-path SBS are covered in Clause 8.
11.6, 11.7, 11.8		Not covered.

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
13		Not covered.
22.1	4.2, annex B, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7 6.1, 6.2, 6.3, If applicable: 8	Partially covered: No specific requirements for lay persons. User and environment of use are factors to include into the design (EN ISO 11607-1:2020/A1:2023) which includes defining the sealing and closure specifications. EN ISO 11607-2:2020/A1:2023 provides the framework for validation of the sealing processes to meet those requirements. The last sentence of GSPR 22.1 is not covered by EN ISO 11607-2:2020/A1:2023.
22.2	4.2, annex B 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 6.1, 6.2, 6.3, If applicable: 8	Partially covered: No specific requirements for lay persons. User and environment of use are factors to include into the design (EN ISO 11607-1:2020/A1:2023) which includes defining the sealing and closure specifications. EN ISO 11607-2:2020/A1:2023 provides the framework for validation of the sealing and assembly processes (manufacturing) to meet those requirements. Dashes 2 and 3 are not covered.
23.3		Not covered.
23.4		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 11607-1	ISO 11607-1:20181 ISO 11607-1:2019/Amd1:2023	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-1:2020 EN ISO 11607-1:2020/A11:2022 EN ISO 11607-1:2020/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.

Second edition
2019-02

AMENDMENT 1
2023-09

Packaging for terminally sterilized medical devices —

Part 2: Validation requirements for forming, sealing and assembly processes

AMENDMENT 1: Application of risk management

Emballages des dispositifs médicaux stérilisés au stade terminal —

Partie 2: Exigences de validation pour les procédés de formage, scellage et assemblage

AMENDEMENT 1: Application de la gestion des risques

Reference number
ISO 11607-2:2019/Amd.1:2023(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Foreword

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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).

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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.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Packaging for terminally sterilized medical devices —

Part 2: Validation requirements for forming, sealing and assembly processes

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 packaged and sterilized.

Clause 2, Normative references

> Correct ISO 11607-1:2018 to ISO 11607-1:2019 and ISO 11607-1:2019/Amd 1:2023.