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DIN EN ISO 11607-2

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Supersedes
DIN EN ISO 11607-2:2017-10

Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019); English version EN ISO 11607-2:2020, English translation of DIN EN ISO 11607-2:2020-05

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte –
Teil 2: Validierungsanforderungen an Prozesse der Formgebung, Siegelung und des Zusammenstellens (ISO 11607-2:2019);
Englische Fassung EN ISO 11607-2:2020,
Englische Übersetzung von DIN EN ISO 11607-2:2020-05

Emballages des dispositifs médicaux stérilisés au stade terminal –
Partie 2: Exigences de validation pour les procédés de formage, scellage et assemblage (ISO 11607-2:2019);
Version anglaise EN ISO 11607-2:2020,
Traduction anglaise de DIN EN ISO 11607-2:2020-05

Document comprises 22 pages

Translation by DIN-Sprachendienst.

In case of doubt, the German-language original shall be considered authoritative.

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A comma is used as the decimal marker.

National foreword

This document (EN ISO 11607-2:2020) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" (Secretariat: USA, ANSI) in collaboration with Technical Committee CEN/TC 102 "Sterilizers and associated equipment for processing of medical devices" (Secretariat: DIN, Germany), with the active participation of German experts.

The responsible German body involved in its preparation was *DIN-Normenausschuss Medizin* (DIN Standards Committee Medicine), Working Committee NA 063-04-04 AA "Sterile supply".

DIN EN ISO 11607 consists of the following parts, under the general title *Packaging for terminally sterilized medical devices:*

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

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

The DIN documents corresponding to the international documents referred to in this document are as follows:

ISO 186	DIN EN ISO 186
ISO 2859-1	DIN ISO 2859-1
ISO 9001	DIN EN ISO 9001
ISO 11139:2018	DIN EN ISO 11139:2019-05
ISO 11607-1	DIN EN ISO 11607-1
ISO 13485:2016	DIN EN ISO 13485:2016-08
ISO 14971	DIN EN ISO 14971
ISO/TS 16775	DIN CEN ISO/TS 16775 (DIN SPEC 58997)

Amendments

This standard differs from DIN EN ISO 11607-2:2017-10 as follows:

a) Annex ZA regarding relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered has been deleted;

b) Annex ZB regarding the relationship between this European Standard and the essential requirements of Directive 90/385/EEC [OJ L 189] aimed to be covered has been deleted;

c) Annex ZC regarding the relationship between this European Standard and the essential requirements of Directive 98/79/EC [OJ L 331] aimed to be covered has been deleted;

d) the definitions have been aligned with the latest version of ISO 11139;

e) terms and definitions for "process variable", "process parameter" and "monitoring of processes" have been added and the term "critical process parameters" has been deleted;

f) the concept of a process specification has been introduced to include all elements required to manufacture a product that consistently meets the specifications;

g) the standard has been editorially revised.

Previous editions

DIN EN ISO 11607-2: 2006-07, 2014-11, 2017-10

National Annex NA
(informative)

Bibliography

DIN CEN ISO/TS 16775 (DIN SPEC 58997), *Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2*

DIN EN ISO 186, *Paper and board — Sampling to determine average quality*

DIN EN ISO 9001, *Quality management systems — Requirements*

DIN EN ISO 11139:2019-05, *Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards* (ISO 11139:2018)

DIN EN ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

DIN EN ISO 13485:2016-08, *Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2016)*

DIN EN ISO 14971, *Medical devices — Application of risk management to medical devices*

DIN ISO 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

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