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DIN EN ISO 11737-2

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Supersedes
DIN EN ISO 11737-2:2010-04

Sterilization of health care products – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019); English version EN ISO 11737-2:2020, English translation of DIN EN ISO 11737-2:2020-07

Sterilisation von Produkten für die Gesundheitsfürsorge –
Mikrobiologische Verfahren –
Teil 2: Prüfungen der Sterilität bei der Definition, Validierung und Aufrechterhaltung eines Sterilisationsverfahrens (ISO 11737-2:2019);
Englische Fassung EN ISO 11737-2:2020,
Englische Übersetzung von DIN EN ISO 11737-2:2020-07

Stérilisation des produits de santé –
Méthodes microbiologiques –
Partie 2: Contrôles de stérilité pratiqués au moment de la définition, de la validation et de la maintenance d'un procédé de stérilisation (ISO 11737-2:2019);
Version anglaise EN ISO 11737-2:2020,
Traduction anglaise de DIN EN ISO 11737-2:2020-07

Document comprises 38 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 11737-2:2020) 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" (Secretariat: BSI, United Kingdom).

The responsible German body involved in its preparation was *DIN-Normenausschuss Medizin* (DIN Standards Committee Medicine), Working Committee NA 063-04-10 AA "Sterilization and processing of medical devices".

DIN EN ISO 11737 consists of the following parts, under the general title *Sterilization of health care products — Microbiological methods:*

— *Part 1: Determination of a population of microorganisms on products*

— *Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*

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

ISO 9000:2015	DIN EN ISO 9000:2015-11
ISO 9001:2015	DIN EN ISO 9001:2015-11
ISO 10012	DIN EN ISO 10012
ISO 11135	DIN EN ISO 11135
ISO 11137-1	DIN EN ISO 11137-1
ISO 11137-2	DIN EN ISO 11137-2
ISO 11138-2	DIN EN ISO 11138-2
ISO 11138-7	DIN EN ISO 11138-7
ISO 11139:2018	DIN EN ISO 11139:2019-05
ISO 11737-1:2018	DIN EN ISO 11737-1:2018-11
ISO 13485:2016	DIN EN ISO 13485:2016-08
ISO 14160	DIN EN ISO 14160
ISO 14644 (all parts)	DIN EN ISO 14644 (all parts)
ISO 14698 (all parts)	DIN EN ISO 14698 (all parts)
ISO 14937	DIN EN ISO 14937
ISO 15189	DIN EN ISO 15189
ISO 17665-1	DIN EN ISO 17665-1
ISO 20857	DIN EN ISO 20857
ISO/IEC 17025:2017	DIN EN ISO/IEC 17025:2018-03

For current information on this document, please go to DIN's website (www.din.de) and search for the document number in question.

Amendments

This standard differs from DIN EN ISO 11737-2:2010-04 as follows:

a) in Clause 2, "Normative references", and Clause 3, "Terms and definitions", the standard has been brought in line with the current rules of presentation;

b) in the Scope, references have been updated and ISO 20857 has been added;

c) terms and definitions have been revised and brought in line with DIN EN ISO 11139 in particular; moreover, the following term has been added: “health care product”, and “growth promotion test” has been deleted;

d) as a result of the inclusion of the informative Annex B, the reference to ISO 15189 specifying requirements for the quality and competence of medical laboratories has been added;

e) a requirement concerning the test samples and an interval of time between the manufacturing of the product and the exposure to the sterilizing agent being as short as possible has been added (5.1.3);

f) a requirement about the samples staying immersed in the culture media and providing a rationale where this is not possible has been added (6.1);

g) a requirement for tests where microorganisms are to be removed from the product by elution has been added in order to carry out a risk assessment to determine the appropriateness of the removal process and the information that all microorganisms may be recovered when using this method has also been added (6.4);

h) additional guidance regarding performing tests of sterility on packaging has been provided, clarifying that package testing is not typically done except when it is an integral part of the product;

i) in Table A.1, additional examples for the selection of the sample item portion have been added;

j) additional guidance regarding what is meant by “controlled environment” for performing tests of sterility (A.6.3) has been provided;

k) additional guidance to discuss circumstances where the method suitability test does not give acceptable results has been provided, stating that after multiple attempts to eliminate inhibitory substances, it is appropriate to accept a reduction of inhibitory substances, with an accompanying rationale and risk assessment (A.6.6);

l) guidance regarding identification of microbial growth in a test of sterility has been provided, saying generally for positive growth the microorganism(s) should be identified (A.6.9);

m) guidance regarding method suitability has been provided, saying that consideration should be given to periodically demonstrating ongoing method suitability in order to ensure that an accumulation of minor changes over time has not occurred (A.7 and A.8);

n) a new informative Annex B on the typical assignment of responsibilities has been included;

o) the informative Annexes ZA, ZB and ZC on the relationship between this European Standard and the essential requirements of EU Directives 90/385/EEC on active implantable medical devices, 93/42/EEC on medical devices and 98/79/EC on in vitro diagnostic medical devices have been brought in line with the current requirements of the European Commission;

p) the informative Annexes ZD and ZE on the relationship between this European Standard and the essential safety and performance requirements of Regulation (EU) 2017/745 on medical devices and the essential safety and performance requirements of Regulation (EU) 2017/746 on in vitro diagnostic medical devices have been included;

q) the standard has been editorially revised.

Previous editions

DIN EN ISO 11737-2: 2000-04, 2010-04

National Annex NA
(informative)

Bibliography

DIN EN ISO 9000:2015-11, *Quality management systems — Fundamentals and vocabulary (ISO 9000:2015)*

DIN EN ISO 9001:2015-11, *Quality management systems — Requirements (ISO 9001:2015)*

DIN EN ISO 10012, *Measurement management systems — Requirements for measurement processes and measuring equipment*

DIN EN ISO 11135, *Sterilization of health care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

DIN EN ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

DIN EN ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

DIN EN ISO 11138-2, *Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes*

DIN EN ISO 11138-7, *Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results*

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 11737-1:2018-11, *Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)*

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

DIN EN ISO 14160, *Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices*

DIN EN ISO 14644 (all parts), *Cleanrooms and associated controlled environments*

DIN EN ISO 14698 (all parts), *Cleanrooms and associated controlled environments — Biocontamination control*

DIN EN ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

DIN EN ISO 15189, *Medical laboratories — Requirements for quality and competence*

DIN EN ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

DIN EN ISO 20857, *Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices*

DIN EN ISO/IEC 17025:2018-03, *General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2017)*