Nederlandse norm

NEN-EN-ISO 11737-2

(en)

Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009,IDT)

Vervangt NEN-EN-ISO 11737-2:2000;
NEN-EN-ISO 11737-2:2008 Ontw.

ICS 07.100.10; 11.080.01

december 2009

Als Nederlandse norm is aanvaard:
- EN ISO 11737-2:2009,IDT
- ISO 11737-2:2009,IDT

Normcommissie 301081 "Steriliseren en steriliteit"

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Nederlands voorwoord

Voor de in deze norm vermelde normatieve verwijzingen bestaan in Nederland de volgende equivalenten:

vermelde norm	Nederlandse norm	titel
ISO 10012	NEN-EN-ISO 10012	Managementsystemen voor metingen - Eisen voor meetprocessen en meetapparatuur
ISO 11737-1:2006	NEN-EN-ISO 11737-1:2006	Sterilisatie van medische hulpmiddelen - Microbiologische methodes - Deel 1: Bepaling van de populatie van micro-organismen op producten
ISO 13485:2003	NEN-EN-ISO 13485:2003	Medische hulpmiddelen - Kwaliteitsmanagementsystemen - Bijzondere eisen voor reguleringsdoeleinden
ISO/IEC 17025:2005	NEN-EN-ISO/IEC 17025:2005	Algemene eisen voor de bekwaamheid van beproevings- en kalibratielaboratoria

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11737-2

November 2009

ICS 07.100.10; 11.080.01

Supersedes EN ISO 11737-2:2000

English Version

Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009)

Stérilisation des dispositifs médicaux - 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 11737-2:2009)

Sterilisation von Medizinprodukten - Mikrobiologische Verfahren - Teil 2: Prüfungen der Sterilität bei der Definition, Validierung und Aufrechterhaltung eines Sterilisationsverfahrens für Medizinprodukte (ISO 11737-2:2009)

This European Standard was approved by CEN on 28 October 2009.

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 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 Management Centre has the same status as the official versions.

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Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 11737-2:2009: E

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Foreword

This document (EN ISO 11737-2:2009) 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 May 2010, and conflicting national standards shall be withdrawn at the latest by May 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 11737-2:2000.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directives.

For relationship with EU Directives, see informative Annexes ZA, ZB and ZC, which are integral parts of this document.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 11737-2:2009 has been approved by CEN as a EN ISO 11737-2:2009 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on Active Implantable Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 90/385/EEC on active implantable medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 90/385/EEC

Clauses of this European Standard	Essential Requirements (ERs) of Directive 90/385/EEC	Qualifying remarks/Notes
4,5,6,7,8	7	This relevant Essential Requirement is only partly addressed in this European Standard

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Annex ZB
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZB.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZB.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clauses of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4,5,6,7,8	8.3	This relevant Essential Requirement is only partly addressed in this European Standard
4,5,6,7,8	8.4	This relevant Essential Requirement is only partly addressed in this European Standard

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