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National Standards Authority of Ireland

IRISH STANDARD

I.S. EN ISO 17665-1:2006

ICS 11.080.01

STERILIZATION OF HEALTH CARE PRODUCTS - MOIST HEAT - PART 1: REQUIREMENTS FOR THE DEVELOPMENT, VALIDATION AND ROUTINE CONTROL OF A STERILIZATION PROCESS FOR MEDICAL DEVICES (ISO 17665-1:2006)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 17665-1

August 2006

ICS 11.080.01

Supersedes EN 554:1994

English Version

Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)

Stérilisation des produits de santé - Chaleur humide - Partie 1: Exigences pour le développement, la validation et le contrôle de routine d'un procédé de stérilisation des dispositifs médicaux (ISO 17665-1:2006)

Sterilisation von Produkten für die Gesundheitsfürsorge - Feuchte Hitze - Teil 1: Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (ISO 17665-1:2006)

This European Standard was approved by CEN on 14 July 2006.

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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 Central Secretariat has the same status as the official versions.

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Foreword

This document (EN ISO 17665-1:2006) 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of an identical text or by endorsement, at the latest by February 2007, and conflicting national standards shall be withdrawn at the latest by August 2009.

This document supersedes EN 554:1994.

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 Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part 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, 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 United Kingdom.

Endorsement notice

The text of ISO 17665-1:2006 has been approved by CEN as EN ISO 17665-1:2006 without any modifications.

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ANNEX ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directives 90/385/EEC, 93/42/EEC and 98/79/EEC

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 EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.

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

Table ZA.1 – Correspondence between this European Standard and Directives 90/385/EEC, 93/42/EEC and 98/79/EC

Clause(s)/Sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 90/385/EEC	Essential Requirements (ERs) of Directive 93/42/EEC	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying remarks/ Notes
4, 5, 6, 7, 8, 9, 10, 11, 12	7	8.3	B.2.3	In part
4, 5, 6, 7, 8, 9, 10, 11, 12		8.4	B.2.4	In part

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

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