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IRISH STANDARD

I.S. EN ISO 22442-3:2007

ICS 11.100.20

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This Irish Standard was published under the authority of the National Standards Authority of Ireland and comes into effect on:
12 February 2008

MEDICAL DEVICES UTILIZING ANIMAL TISSUES AND THEIR DERIVATIVES - PART 3: VALIDATION OF THE ELIMINATION AND/OR INACTIVATION OF VIRUSES AND TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (TSE) AGENTS (ISO 22442-3:2007)

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EUROPEAN STANDARD

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EN ISO 22442-3

December 2007

ICS 11.100.20

Supersedes EN 12442-3:2000

English Version

Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents (ISO 22442-3:2007)

Dispositifs médicaux utilisant des tissus animaux et leurs dérivés - Partie 3: Validation de l'élimination et/ou de l'inactivation des virus et autres agents responsables d'encéphalopathie spongiforme transmissible (EST) (ISO 22442-3:2007)

Tierische Gewebe und deren Derivate, die zur Herstellung von Medizinprodukten eingesetzt werden - Teil 3: Validierung der Eliminierung und/oder Inaktivierung von Viren und Erregern der übertragbaren spongiösen Enzephalopathie (TSE) (ISO 22442-3:2007)

This European Standard was approved by CEN on 14 December 2007.

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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 CEN Management Centre has the same status as the official versions.

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Foreword

This document (EN ISO 22442-3:2007) has been prepared by Technical Committee ISO/TC 194 "Biological evaluation of medical devices" in collaboration with Technical Committee CEN/TC 316 “Medical devices utilizing tissues” the secretariat of which is held by NBN.

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of an identical text or by endorsement, at the latest by June 2008, and conflicting national standards shall be withdrawn at the latest by June 2008.

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 12442-3:2000.

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 EC Directive(s).

This European Standard has been developed for medical devices regulated by the Medical Device Directive 93/42/EC as amended by 2003/32/EC (see Annex ZA). By analogy, it could be applied for active implantable medical devices regulated by the Active Implantable Medical Device Directive 90/385/EC.

For relationship with EC 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, 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 22442-3:2007 has been approved by CEN as a EN ISO 22442-3:2007 without any modification.

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Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC as amended by Commission Directive 2003/32/EC

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, concerning medical devices, as amended by Commission Directive 2003/32/EC in relation to detailed specifications regarding requirements for medical devices utilizing tissues of animal origin.

Once this 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 clauses of this standard given in table ZA confers, within the limits of the scope of this International Standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA — Correspondence between this European Standard and Directive 93/42/EEC as amended by Commission Directive 2003/32/EC

Clause(s)/subclause(s) of this International Standard	Essential requirements (ERs) of Directive 93/42/EEC as amended by Commission Directive 2003/32/EC	Qualifying remarks/Notes
4, 5, 6, 7, 8, 9, Annex A	Annex I, 7.1, 7.2, 8.1, 8.2	
4, 5, 6, 7, 8, 9, Annex A	Annex of Commission Directive 2003/32/EC	

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

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