BS EN ISO 22442-2:2015

BSI Standards Publication

Medical devices utilizing animal tissues and their derivatives

Part 2: Controls on sourcing, collection and handling

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National foreword

This British Standard is the UK implementation of EN ISO 22442-2:2015. It supersedes BS EN ISO 22442-2:2007 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee RGM/1, Regenerative medicine.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 December 2015.

Amendments/corrigenda issued since publication

Date	Text affected

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 22442-2

November 2015

ICS 11.100.99

Supersedes EN ISO 22442-2:2007

English Version

Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling (ISO 22442-2:2015)

Dispositifs médicaux utilisant des tissus animaux et leurs dérivés - Partie 2: Contrôles de l'origine, de la collecte et du traitement (ISO 22442-2:2015)

Tierische Gewebe und deren Derivate, die zur Herstellung von Medizinprodukten eingesetzt werden - Teil 2: Kontrollen der Beschaffung, Materialgewinnung und Handhabung (ISO 22442-2:2015)

This European Standard was approved by CEN on 31 October 2015.

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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-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (EN ISO 22442-2:2015) 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 DIN.

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 2016 and conflicting national standards shall be withdrawn at the latest by May 2016.

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 22442-2:2007.

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, see informative Annex ZA, which is an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard ‘within the meaning of Annex ZA’, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table 1 – Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 22442-1	EN ISO 22442-1:2016	ISO 22442-1:2016

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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta,

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