



BSI Standards Publication

Medical devices utilizing animal tissues and their derivatives

Part 1: Application of risk management

National foreword

This British Standard is the UK implementation of EN ISO 22442-1:2020. It is identical to ISO 22442-1:2020. It supersedes BS EN ISO 22442-1:2015, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/194, Biological evaluation of medical devices.

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

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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Amendments/corrigenda issued since publication

Date	Text affected
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EUROPEAN STANDARD
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EN ISO 22442-1

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Supersedes EN ISO 22442-1:2015

English Version

Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management (ISO 22442-1:2020)

Dispositifs médicaux utilisant des tissus animaux et leurs dérivés - Partie 1: Application de la gestion des risques (ISO 22442-1:2020)

Tierische Gewebe und deren Derivate, die zur Herstellung von Medizinprodukten eingesetzt werden - Teil 1: Anwendung des Risikomanagements (ISO 22442-1:2020)

This European Standard was approved by CEN on 2 December 2020.

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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
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 22442-1:2020) has been prepared by Technical Committee ISO/TC 194 "Biological and clinical evaluation of medical devices" in collaboration with Technical Committee CEN/TC 206 "Biological and clinical evaluation of medical devices" 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 June 2021, and conflicting national standards shall be withdrawn at the latest by June 2021.

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

This document supersedes EN ISO 22442-1:2015.

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 the relationship with EU Directive(s) 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 references documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlations 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 or IEC
ISO 10993-1	EN ISO 10993-1:2020	ISO 10993-1:2018
ISO 14971	EN ISO 14971:2019	ISO 14971:2019
ISO 22442-2:2020	EN ISO 22442-2:2020	ISO 22442-2:2020
ISO 22442-3:2007	EN ISO 22442-3:2007	ISO 22442-3:2007

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Endorsement notice

The text of ISO 22442-1:2020 has been approved by CEN as EN ISO 22442-1:2020 without any modification.