



BSI Standards Publication

Medical devices utilizing animal tissues and their derivatives

Part 2: Controls on sourcing, collection and handling

National foreword

This British Standard is the UK implementation of EN ISO 22442-2:2020. It is identical to [ISO 22442-2:2020](#). It supersedes [BS EN ISO 22442-2:2015](#), which is withdrawn.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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English Version

Medical devices utilizing animal tissues and their
derivatives - Part 2: Controls on sourcing, collection and
handling (ISO 22442-2:2020)

Dispositifs médicaux utilisant des tissus animaux
et leurs dérivés - Partie 2: Contrôles de l'origine, de
la collecte et du traitement (ISO 22442-2:2020)

Tierische Gewebe und deren Derivate, die
zur Herstellung von Medizinprodukten
eingesetzt werden - Teil 2: Kontrollen der
Beschaffung, Materialgewinnung und
Handhabung (ISO 22442-2:2020)

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

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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 22442-2:2020) 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of an identical text or by endorsement, at the latest by June 2021, and conflicting national standards shall be withdrawn at the latest by June 2021.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 22442-2:2015.

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 22442-1	EN ISO 22442-1:2020	ISO 22442-1:2020

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Endorsement notice

The text of [ISO 22442-2:2020](#) has been approved by CEN as EN ISO 22442-2:2020 without any modification.