



SLOVENSKI STANDARD SIST EN ISO 22442-2:2016

01-februar-2016

Nadomešča:

SIST EN ISO 22442-2:2008

**Medicinski pripomočki, ki uporabljajo živalska tkiva in njihove derivate - 2. del:
Nadzor pri nabavi, zbiranju in ravnanju (ISO 22442-2:2015)**

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

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)

Ta slovenski standard je istoveten z: EN ISO 22442-2:2015

ICS:

11.120.01 Farmacija na splošno Pharmaceutics in general

SIST EN ISO 22442-2:2016 en

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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)

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

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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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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Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 22442-2:2015 has been approved by CEN as EN ISO 22442-2:2015 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

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 the Essential Requirements of Directive 93/42/EEC, concerning medical devices, as amended by Commission Regulation (EU) No722/2012 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 Union 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 given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA Regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC, as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

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NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC as amended by Commission Regulation (EU) No 722/2012

Clause(s)/sub-clause(s) of this International Standard	Essential Requirements (ERs) of Directive 93/42/EEC as amended by Commission Regulation No 722/2012	Qualifying remarks/Notes
4, 5, 6, 7, 8 and Annex A	7.1	Annex B includes suggested format for Certificates for animal materials to be used for medical devices. Annex C offers advice on the assessment of veterinary services.
4, 5, 6, 7, 8 and Annex A	7.2	Annex B includes suggested format for Certificates for animal materials to be used for medical devices. Annex C offers advice on the assessment of veterinary services.
4, 5, 6, 7, 8 and Annex A	8.1	Annex B includes suggested format for Certificates for animal materials to be used for medical devices. Annex C offers advice on the assessment of veterinary services.
4, 5, 6, 7, 8 and Annex A	8.2	Annex B includes suggested format for Certificates for animal materials to be used for medical devices. Annex C offers advice on the assessment of veterinary services.
4, 5, 6, 7, 8 and Annex A	Annex I of Commission Regulation No 722/2012	

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

INTERNATIONAL
STANDARD

ISO
22442-2

Second edition
2015-11-01

**Medical devices utilizing animal
tissues and their derivatives —**

**Part 2:
Controls on sourcing, collection and
handling**

iTeh STANDARD PREVIEW
Dispositifs médicaux utilisant des tissus animaux et leurs dérivés —
(standards.itih.ai) Partie 2: Contrôles de l'origine, de la collecte et du traitement

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