SLOVENSKI STANDARD
SIST EN ISO 22442-2:2021

01-februar-2021

Nadomešča:
SIST EN ISO 22442-2:2016

Medicinski pripomočki, ki uporabljajo živalska tkiva in njihove derivate - 2. del: Nadzor pri nabavi, zbiranju in ravnanju z njimi (ISO 22442-2:2020)

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

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)

Ta slovenski standard je istoveten z: **EN ISO 22442-2:2020**

ICS:

11.040.99	Druga medicinska oprema	Other medical equipment
11.120.01	Farmacija na splošno	Pharmaceutics in general

SIST EN ISO 22442-2:2021 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 22442-2

December 2020

ICS 11.100.20

Supersedes EN ISO 22442-2:2015

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)

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

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.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 22442-2:2020 E

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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

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

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

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC as amended by Commission Regulation (EU) No 722/2012

This European Standard has been prepared under a Commission's standardization request [M/023 concerning the development of European Standards related to medical devices] to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA 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.

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, it means that it is not addressed by this European Standard.

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

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
7.1 first indent only	4 ,5, 6, 7, 8 and Annex A	Covered for the sourcing, collection and handling of materials of animal origin chosen for the manufacture of medical devices. Not covered for flammability. Not covered for manufacture.
7.2 first sentence only	4 ,5, 6, 7, 8 and Annex A	Covered for reducing risks to patients resulting from contaminants as far as the sourcing, collection and handling of materials used in medical devices based on animal tissues and their derivatives is concerned, providing any resulting risks are minimized. Not covered for packing, manufacture, transport or storage.

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
8.1 first sentence only	4 ,5, 6, 7, 8 and Annex A	Covered for reducing risks of infection to patients as far as the sourcing, collection and handling of materials used in medical devices based on animal tissues and their derivatives is concerned, providing any resulting risks are eliminated or reduced as far as possible. Not covered for manufacture.
8.2 first paragraph of third paragraph only	4 ,5, 6, 7, 8 and Annex A	Covered for the handling of materials used in medical devices based on animal tissues and their derivatives
Annex I of Commission Regulation (EU) No 722/2012	4 ,5, 6, 7, 8 and Annex A	The requirements detailed in Section 1 of Annex I of Reg. 722/2012/EC cover risk analysis and risk management of medical devices manufactured utilising non-viable tissues, or derivatives thereof, sourced from animals that are susceptible to TSEs, as defined in Art. 1.2. The Regulation is therefore specific to TSE risks. Annex I of the Regulation requires implementation of risk control measures, including controls on sourcing, collection and handling of animal-derived material, to manage TSE risks.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 22442-2

Third edition
2020-09

Medical devices utilizing animal tissues and their derivatives —

Part 2: Controls on sourcing, collection and handling

Dispositifs médicaux utilisant des tissus animaux et leurs dérivés — Partie 2: Contrôles de l'origine, de la collecte et du traitement

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