DIN EN ISO 22442-2

ICS 11.100.20

Supersedes
DIN EN ISO 22442-2:2016-05

Medical devices utilizing animal tissues and their derivatives – Part 2: Controls on sourcing, collection and handling (ISO 22442-2:2020); English version EN ISO 22442-2:2020, English translation of DIN EN ISO 22442-2:2021-04

Tierische Gewebe und deren Derivate, die zur Herstellung von Medizinprodukten eingesetzt werden –
Teil 2: Kontrollen der Beschaffung, Materialgewinnung und Handhabung (ISO 22442-2:2020);
Englische Fassung EN ISO 22442-2:2020,
Englische Übersetzung von DIN EN ISO 22442-2:2021-04

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);
Version anglaise EN ISO 22442-2:2020,
Traduction anglaise de DIN EN ISO 22442-2:2021-04

Document comprises 27 pages

Translation by DIN-Sprachendienst.

In case of doubt, the German-language original shall be considered authoritative.

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A comma is used as the decimal marker.

National foreword

This document (EN ISO 22442-2:2020) has been prepared by Technical Committee ISO/TC 194 "Biological and clinical evaluation of medical devices", Subcommittee SC 1 "Tissue product safety" in collaboration with Technical Committee CEN/TC 206 "Biological and clinical evaluation of medical devices" (Secretariat: DIN, Germany).

The responsible German body involved in its preparation was *DIN-Normenausschuss Feinmechanik und Optik* (DIN Standards Committee Optics and Precision Mechanics), Working Committee NA 027-05-10 AA "Medical devices utilizing tissues".

The DIN documents corresponding to the documents referred to in this document are as follows:

ISO 9001	DIN EN ISO 9001
ISO 13485	DIN EN ISO 13485
ISO 14971:2007	DIN EN ISO 14971:2007-07
ISO 22442-1	DIN EN ISO 22442-1
ISO 22442-3	DIN EN ISO 22442-3

For current information on this document, please go to DIN's website (www.din.de) and search for the document number in question.

Amendments

This standard differs from DIN EN ISO 22442-2:2016-05 as follows:

a) the weblink on the stunning technique in A.3.2.5, Note 1 has been updated;

b) in the Scope, a clarification on cervid-sourced materials and other TSE susceptible species has been included;

c) a clarification on atypical BSE types has been included, especially in combination with intracranial applications;

d) improved notes on the expectation of using validated biochemical testing to establish TSE presence have been included;

e) the informative Annex ZA on the relationship between this European Standard and the Essential Requirements of the EU Directive on Medical Devices has been revised.

Previous editions

DIN EN 12442-2: 2001-01
DIN EN ISO 22442-2: 2008-03, 2016-05

National Annex NA
(informative)

Bibliography

DIN EN ISO 9001, *Quality management systems — Requirements*

DIN EN ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

DIN EN ISO 14971:2007-07, *Medical devices — Application of risk management to medical devices (ISO 14971:2007)*

DIN EN ISO 22442-1, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management*

DIN EN ISO 22442-3, *Medical devices utilizing animal tissues and their derivatives — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents*

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