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Supersedes
DIN EN ISO 22442-1:2021-04

Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management (ISO 22442-1:2020); English version EN ISO 22442-1:2020, English translation of DIN EN ISO 22442-1:2021-08

Tierische Gewebe und deren Derivate, die zur Herstellung von Medizinprodukten eingesetzt werden –
Teil 1: Anwendung des Risikomanagements (ISO 22442-1:2020);
Englische Fassung EN ISO 22442-1:2020,
Englische Übersetzung von DIN EN ISO 22442-1:2021-08

Dispositifs médicaux utilisant des tissus animaux et leurs dérivés –
Partie 1: Application de la gestion des risques (ISO 22442-1:2020);
Version anglaise EN ISO 22442-1:2020,
Traduction anglaise de DIN EN ISO 22442-1:2021-08

Document comprises 40 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 22442-1:2020) 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 10993-1	DIN EN ISO 10993-1
ISO 10993-2	DIN EN ISO 10993-2
ISO 10993-3	DIN EN ISO 10993-3
ISO 10993-4	DIN EN ISO 10993-4
ISO 10993-5	DIN EN ISO 10993-5
ISO 10993-6	DIN EN ISO 10993-6
ISO 10993-7	DIN EN ISO 10993-7
ISO 10993-9	DIN EN ISO 10993-9
ISO 10993-10	DIN EN ISO 10993-10
ISO 10993-11	DIN EN ISO 10993-11
ISO 10993-12	DIN EN ISO 10993-12
ISO 10993-13	DIN EN ISO 10993-13
ISO 10993-14	DIN EN ISO 10993-14
ISO 10993-15	DIN EN ISO 10993-15
ISO 10993-16	DIN EN ISO 10993-16
ISO 10993-17	DIN EN ISO 10993-17
ISO 10993-18	DIN EN ISO 10993-18
ISO 11135 (all parts)	DIN EN ISO 11135 (all parts)
ISO 11137 (all parts)	DIN EN ISO 11137 (all parts)
ISO 11737 (all parts)	DIN EN ISO 11737 (all parts)
ISO 13408-1	DIN EN ISO 13408-1
ISO 13408-2	DIN EN ISO 13408-2
ISO 13408-3	DIN EN ISO 13408-3
ISO 13408-4	DIN EN ISO 13408-4
ISO 13408-5	DIN EN ISO 13408-5
ISO 13408-6	DIN EN ISO 13408-6
ISO 13408-7	DIN EN ISO 13408-7
ISO 13485	DIN EN ISO 13485
ISO 14160	DIN EN ISO 14160
ISO 14937	DIN EN ISO 14937
ISO 14971	DIN EN ISO 14971
ISO 17664	DIN EN ISO 17664
ISO 17665-1	DIN EN ISO 17665-1
ISO 22442-2	DIN EN ISO 22442-2
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.

Users of the German version of this standard should note the following: The term **"sourcing"** has been translated as ***"Beschaffung"***. **"Procurement"** is synonymous with "sourcing" and has also been translated as ***"Beschaffung"***. **"Source"** has been translated as ***"Herkunft"*** and **"collection"** has been translated as***"Materialgewinnung"***.

Amendments

This standard differs from DIN EN ISO 22442-1:2016-05 as follows:

a) 4.4.2 has been updated;

b) weblinks in C.2, bullet point 1, C.3.3 and C.4.4 have been updated;

c) the weblink in D.3.3 has been updated;

d) C.10 has been added;

e) the Bibliography has been updated.

Compared with DIN EN ISO 22442-1:2021-04, the following corrections have been made to the German version:

a) in Clause C.10, third bullet point, *"Mindestalter von 30 Monaten für Kälber"* has been replaced by *"Höchstalter von 30 Monaten für Kälber"*;

b) in D.3.1, Table D.2, in the table heading, the footnote symbol a has been removed 4 times for infectivity.

Previous editions

DIN EN 12442-1: 2001-01
DIN EN ISO 22442-1: 2008-03, 2016-05, 2021-04

National Annex NA
(informative)

Bibliography

DIN EN ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

DIN EN ISO 10993-2, *Biological evaluation of medical devices — Part 2: Animal welfare requirements*

DIN EN ISO 10993-3, *Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*

DIN EN ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

DIN EN ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

DIN EN ISO 10993-6, *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation*

DIN EN ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

DIN EN ISO 10993-9, *Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products*

DIN EN ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization*

DIN EN ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

DIN EN ISO 10993-12, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*

DIN EN ISO 10993-13, *Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymeric medical devices*

DIN EN ISO 10993-14, *Biological evaluation of medical devices — Part 14: Identification and quantification of degradation products from ceramics*

DIN EN ISO 10993-15, *Biological evaluation of medical devices — Part 15: Identification and quantification of degradation products from metals and alloys*

DIN EN ISO 10993-16, *Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables*

DIN EN ISO 10993-17, *Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances*

DIN EN ISO 10993-18, *Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process*

DIN EN ISO 11135 (all parts), *Sterilization of health care products — Ethylene oxide*

DIN EN ISO 11137 (all parts), *Sterilization of health care products — Radiation*

DIN EN ISO 11737 (all parts), *Sterilization of health care products — Microbiological methods*

DIN EN ISO 13408-1, *Aseptic processing of health care products — Part 1: General requirements*

DIN EN ISO 13408-2, *Aseptic processing of health care products — Part 2: Sterilizing filtration*

DIN EN ISO 13408-3, *Aseptic processing of health care products — Part 3: Lyophilization*

DIN EN ISO 13408-4, *Aseptic processing of health care products — Part 4: Clean-in-place technologies*

DIN EN ISO 13408-5, *Aseptic processing of health care products — Part 5: Sterilization in place*

DIN EN ISO 13408-6, *Aseptic processing of health care products — Part 6: Isolator systems*

DIN EN ISO 13408-7, *Aseptic processing of health care products — Part 7: Alternative processes for medical devices and combination products*

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

DIN EN ISO 14160, *Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices*

DIN EN ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

DIN EN ISO 14971, *Medical devices — Application of risk management to medical devices*

DIN EN ISO 17664, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

DIN EN ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

DIN EN ISO 22442-2, *Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling*

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*