

DIN EN ISO 22442-3



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Supersedes
DIN EN 12442-3:2001-01

**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
(ISO 22442-3:2007)
English version of DIN EN ISO 22442-3:2008-03**

Tierische Gewebe und deren Derivate, die zur Herstellung von Medizinprodukten
eingesetzt werden –

Teil 3: Validierung der Eliminierung und/oder Inaktivierung von Viren und Erregern der
übertragbaren spongiösen Enzephalopathie (TSE) (ISO 22442-3:2007)

Englische Fassung DIN EN ISO 22442-3:2008-03

Document comprises 29 pages



National foreword

This standard has been prepared by Technical Committee CEN/TC 316 “Medical devices utilizing tissues” (Secretariat: NBN, Belgium) in collaboration with Technical Committee ISO/TC 194/SC 1 “Tissue product safety”.

The responsible German body involved in its preparation was the *Normenausschuss Feinmechanik und Optik* (Optics and Precision Mechanics Standards Committee), Technical Committee NA 027-02-21 *AA Medizinische Produkte auf Basis des Tissue Engineering*.

The DIN Standards corresponding to the International Standards referred to in clause 2 of the EN are as follows:

ISO 22442-1:2007	DIN EN ISO 22442-1:2008-03
ISO 22442-2	DIN EN ISO 22442-2

Note to the translation:

The following terms were used in the translation:

Sourcing		Beschaffung
Procurement	(as a synonym of sourcing)	Beschaffung
Source		Herkunft
Collection		Materialgewinnung

Amendments

This standard differs from DIN EN 12442-3:2001-01 as follows:

- a) The original European document has been adapted to take account of international needs.
- b) Annex A (normative) “Requirements related to literature review” has been completely revised.
- c) Annex C “Guidance on the elimination and/or inactivation study for TSE agents” has been completely revised.

Previous editions

DIN EN 12442-3: 2001-01

National Annex NA (informative)

Bibliography

DIN EN ISO 22442-1:2008-03, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management (ISO 22442-1:2007)*

DIN EN ISO 22442-2, *Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling (ISO 22442-2:2007)*

English Version

**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
(ISO 22442-3:2007)**

Dispositifs médicaux utilisant des tissus animaux et leurs dérivés - Partie 3: Validation de l'élimination et/ou de l'inactivation des virus et autres agents responsables d'encéphalopathie spongiforme transmissible (EST) (ISO 22442-3:2007)

Tierische Gewebe und deren Derivate, die zur Herstellung von Medizinprodukten eingesetzt werden - Teil 3: Validierung der Eliminierung und/oder Inaktivierung von Viren und Erregern der übertragbaren spongiösen Enzephalopathie (TSE) (ISO 22442-3:2007)

This European Standard was approved by CEN on 14 December 2007.

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