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DIN EN ISO 14630

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Supersedes
DIN EN ISO 14630:2009-08

Non-active surgical implants – General requirements (ISO 14630:2012); English version EN ISO 14630:2012, English translation of DIN EN ISO 14630:2013-03

Nichtaktive chirurgische Implantate – Allgemeine Anforderungen (ISO 14630:2012); Englische Fassung EN ISO 14630:2012, Englische Übersetzung von DIN EN ISO 14630:2013-03

Implants chirurgicaux non actifs – Exigences générales (ISO 14630:2012); Version anglaise EN ISO 14630:2012, Traduction anglaise de DIN EN ISO 14630:2013-03

Document comprises 23 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 14630:2012) has been prepared by Technical Committee ISO/TC 150 “Implants for surgery” in collaboration with Technical Committee CEN/TC 285 “Non-active surgical implants” (Secretariat: DIN, Germany).

The responsible German body involved in its preparation was the *Normenausschuss Feinmechanik und Optik* (Optics and Precision Mechanics Standards Committee), Working Committee NA 027-02-17 AA *Chirurgische Implantate.*

The DIN Standards corresponding to the International Standards referred to in Clause 2 of this standard are as follows:

ISO 8601	DIN ISO 8601
ISO 10993-1	DIN EN ISO 10993-1
ISO 10993-7	DIN EN ISO 10993-7
ISO 11135-1	DIN EN ISO 11135-1
ISO 11137-1	DIN EN ISO 11137-1
ISO 11137-2	DIN EN ISO 11137-2
ISO 11607-1	DIN EN ISO 11607-1
ISO 13408-1	DIN EN ISO 13408-1
ISO 14155	DIN EN ISO 14155
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 22442-1	DIN EN ISO 22442-1
ISO 22442-2	DIN EN ISO 22442-2
ISO 22442-3	DIN EN ISO 22442-3
ISO 80000 (all parts)	DIN EN ISO 80000 (all parts)

Amendments

This standard differs from DIN EN ISO 14630:2009-08 as follows:

a) Clause 5 “Design attributes” has been extended to include anatomical features, pathology of the host tissue and information how to reduce the risk of use error;

b) Subclause 7.2 “Pre-clinical evaluation” has been extended in particular with regard to the results of biophysical and modelling research;

c) Subclause 11.3 “Instructions for use” has been extended to include the date of the latest revision of the instructions for use;

d) Annex ZA has been brought in line with the requirements of the European Commission.

Previous editions

DIN 58800: 1971-11
DIN 58800-1: 1980-01
DIN EN ISO 14630: 1997-12, 2005-08, 2008-04, 2009-08

National Annex NA
(informative)

Bibliography

DIN ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

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

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

DIN EN ISO 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

DIN EN ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

DIN EN ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

DIN EN ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

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

DIN EN ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

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, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable 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 22442-1, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management*

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*

DIN EN ISO 80000 (all parts), *Quantities and units*

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