INTERNATIONAL STANDARD

ISO 14630

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Non-active surgical implants — General requirements

Implants chirurgicaux non actifs — Exigences générales

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 14630 was prepared by the European Committee for Standardization (CEN) in collaboration with ISO Technical Committee TC 150, *Implants for surgery*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Annex A of this International Standard is for information only.

Clause A.3 of annex A provides a list of corresponding International and European Standards for which equivalents are not given in the text.

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Foreword

The text of EN ISO 14630:1997 has been prepared by Technical Committee CEN/TC 285 "Non-active surgical implants", the secretariat of which is held by NNI, in collaboration with Technical Committee ISO/TC 150 "Implants for surgery".

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of an identical text or by endorsement, at the latest by May 1998, and conflicting national standards shall be withdrawn at the latest by May 1998.

This European Standard 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).

There are three levels of European Standards dealing with non-active surgical implants. These are as follows, with level 1 being the highest:

- level 1: General requirements for non-active surgical implants;

- level 2: Particular requirements for families of non-active surgical implants;

- level 3: Specific requirements for types of non-active surgical implants.

This standard is a level 1 standard and contains requirements that apply to all non-active surgical implants. It also indicates that there are additional requirements in the level 2 and level 3 standards.

The level 2 standards apply to a more restricted set or family of implants such as those designed for use in osteosynthesis, cardiovascular surgery, or joint replacement.

The level 3 standards apply to specific types of implants within a family such as hip joints or mammary implants. All European Standards currently available or in preparation are listed in the bibliography (see Annex A).

To address all requirements, it is necessary to start with a standard of the lowest available level.

References to other European or International Standards can also be found in Annex A "Bibliography".

NOTE: The European Standards listed in the bibliography have not been adopted as International Standards in all cases (see also notes in Introduction and clause 2).

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard provides a method to demonstrate compliance with the relevant essential requirements as outlined in general terms in Annex 1 of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as they apply to non-active surgical implants, hereafter referred to as implants. It also provides a method of addressing the fundamental principles outlined in ISO/TR 14283, as they apply to non active surgical implants.
For such products, particular and specific requirements may apply. These additional requirements are specified in the level 2 and 3 standards or their parts.

NOTE: The structure of this standard and the normative references of this standard are based on the use of the standard in supporting Council Directive 93/42/EEC.
For the European Standards listed in the normative references (see clause 2), in some cases International Standards are available (see also clause 2, NOTE 1). Users of International Standards should be aware that they may not necessarily meet the essential requirements of the Council Directive 93/42/EEC or other regulatory requirements for other countries or regions.

1 Scope

This European Standard specifies general requirements for non-active surgical implants. This standard is not applicable to dental implants, dental restorative materials, transendodontic and transradicular implants and intra-ocular lenses.

With regard to safety, this standard gives requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging and information supplied by the manufacturer, and tests.
Tests required to be used to demonstrate compliance with this standard are contained in other levels.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 540	Clinical investigations of medical devices for human subjects.
EN 550	Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization.
EN 552	Sterilization of medical devices - Validation and routine control of sterilization by irradiation.
EN 554	Sterilization of medical devices - Validation and routine control of steam sterilization by moist heat.
EN 556	Sterilization of medical devices - Requirements for medical devices labelled "Sterile".
EN 868-1	Packaging materials for sterilization of wrapped goods - Part 1: General requirements and requirements for the validation of packaging for terminally sterilized devices.
EN 980	Terminology, symbols and information provided with medical devices - Graphical symbols for use in the labelling of medical devices.
prEN 1041	Terminology, symbols and information provided with medical devices - Information supplied by the manufacturer with medical devices.
prEN 1441	Medical devices - Risk analysis.
prEN ISO 10993-1	Biological evaluation of medical and dental materials and devices - Part 1: Guidance on selection of tests.

NOTE 1: For some of the European Standards listed in this clause, an identical or technically related International Standards is available. These International Standards are listed in A.3.

NOTE 2: Annex A "Bibliography" summarizes informative references to other parts of this standard and other European Standards, as well as informative references which are cited in the text.

3 Definitions

For the purposes of this European Standard the following definitions apply:

3.1 non-active surgical implant: Implantable device which is not an active medical device.

3.2 implantable device: Device which is intended:

- to be totally introduced into the human body or,
- to replace an epithelial surface or the surface of the eye,

by surgical intervention which is intended to remain in place after the procedure.
Any medical device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

3.3 active medical device: Medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change are not considered to be active medical devices.

3.4 safety: Freedom from unacceptable risk of harm.

3.5 implantable state: Condition of an implant prepared for implantation into a human subject.

3.6 leakage: Unintended movement of fluid including body fluids into or out of implants through a defect in the structure of the containing wall.

3.7 coating: Layer of material used to cover or partially cover a surface of an implant.

4 Intended performance

The intended performance of an implant shall be described and documented by addressing the following:

- functional characteristics;
- typical intended applications;
- intended conditions of use;

with particular regard to safety.

NOTE: Account should be taken of:

- published standards;
- published clinical and scientific literature;
- validated test results.

5 Design attributes

The design attributes to meet the intended performance shall take into account at least the following:

a) materials and their biocompatibility (see clause 6);
b) physical, mechanical and chemical properties of materials, including endurance properties and ageing (see clauses 6 and 7);
c) wear characteristics of materials and the effects of wear and wear products on the implant and the body (see clauses 6 and 7);
d) effect of manufacturing processes (including sterilization) on material characteristics and performance (see clauses 6, 7, 8 and 9);
e) possible effects on the implant and its function due to interactions between its constituent materials and other materials and substances (see clauses 6 and 7);
f) extent and effect of leakage and/or diffusion of substances used to fill implants (see clauses 6 and 7);
g) interconnections and their effects on the intended performance (see clause 7);
h) interface(s) between the implant and body tissue(s), particularly relative to fixation and connection, and surface conditions (see clause 7);
i) shape and dimensions including their possible effects on tissues and body fluids (see clause 7);
j) biocompatibility of the implant in its implantable state (see clauses 6 and 7);
k) physical and chemical effects of the body and external environment on the implant (see clause 7);
l) effects of radiation and electromagnetic fields on the implant and consequential effects on the body (see clauses 6.1 and 7);
m) ability to implant, to remove and to replace the implant after implantation (see clause 7);
n) microbiological and particulate contamination levels (see clauses 8, 9 and 10);
o) suitability and effectiveness of packaging (see clause 10).

Implant design attributes shall be documented. Where any of the above design attributes are not considered to be applicable, the reason shall be documented and justified.

6 Materials

Materials for the manufacture of implants shall be selected with regard to the properties required for the intended purpose, taking into account the effects of manufacture, handling, sterilization and storage. Possible reactions of implants with human tissues and body fluids, other materials, other implants, substances, gases, radiation and electromagnetic fields shall be considered (see clause 7).

When a medicinal product is an integral part of an implant, the medicinal product shall be assessed according to pharmaceutical principles. The performance of the medicinal product used in combination with the implant shall not be affected by the implant and/or visa versa.

NOTE 1: For complying with the provisions of the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, the safety, quality and usefulness of the medicinal product should be verified, taking into account of the intended purpose of the implant by analogy with the appropriate methods specified in Directive 75/318/EEC.