

Instrumentation to be used in association with non-active surgical implants — General requirements

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British Standard

ICS 11.040.30

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Summary of pages

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English version

Instrumentation to be used in association with non-active surgical implants — General requirements

L'instrumentation devant être utilisée en association
avec les implants chirurgicaux non actifs —
Exigences générales

Instrumente die in Verbindung mit nichtaktiven
chirurgischen Implantaten verwendet werden —
Allgemeine Anforderungen

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 285, Non-active surgical implants, the secretariat of which is held by NNI.

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of an identical text or by endorsement, at the latest by July 1998, and conflicting national standards shall be withdrawn at the latest by July 1998.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

This standard contains requirements that apply to instruments to be used in association with non-active surgical implants.

References can be found in annex A (informative) “Bibliography”.

For relationship with EU Directive(s), see informative annex C, which is an integral part of this standard.

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.

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Introduction

This European Standard provides a method to demonstrate compliance with the relevant Essential Requirements (ERs) 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 instrumentation which is to be used in association with non-active surgical implants, hereafter referred to as instruments.

1 Scope

This European Standard specifies general requirements for instruments to be used in association with non-active surgical implants. These requirements apply to instruments when they are manufactured and when they are re-supplied after refurbishment.

This standard applies to instruments which may be connected to powered driven systems, but does not apply to the powered driven system itself.

This standard is not applicable to instruments associated with dental implants, transendodontic and transradicular implants and ophthalmic implants.

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.

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 addition 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 sterilization by moist heat*.

EN 556, *Sterilization of medical devices — Sterility assurance level for medical devices labelled “Sterile” — Requirements*.

EN 868-1, *Packaging materials and systems for medical devices which are to be sterilized — Part 1: General requirements and test methods*.

EN 980, *Graphical symbols for use in the labelling of medical devices*.

EN 1041:1998, *Information supplied by the manufacturer with medical devices*.

EN 1441, *Medical devices — Risk analysis*.

NOTE Annex A summarizes informative references to standards for “non-active” surgical implants and to informative referenced harmonized European Standards. These informative references are cited at the appropriate places in the text.

3 Definitions

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

3.1

associated instrument (instrument)

non-active medical device intended for use during surgical procedures related to a specific non-active surgical implant

3.2

re-supplied instrument

instrument or set of instruments that has been returned to the manufacturer and has been re-issued

4 Intended performance

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

- a) functional characteristics;
- b) intended conditions of use.

NOTE Account should be taken of:

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

The extent to which the intended performance has been achieved shall be determined (see clause 7).

5 Design attributes

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

- a) physical, mechanical and chemical properties of the instrument materials (see clauses 6 and 7);
- b) microbiological and particulate contamination levels (see clauses 7, 9 and 10);
- c) the ease of use, cleaning and maintenance (see clause 7);
- d) the potential deterioration of the material characteristics due to sterilization and storage (see clauses 6, 7 and 8);
- e) the effects of contact between the instrument and body, the implant and other instruments (see clause 7);
- f) shape and dimensions including their possible effects on the body (see clause 7);
- g) wear characteristics of materials and the effect of wear and wear products on the instrument and the body (see clauses 6 and 7);
- h) insertion, removal and interconnecting parts (see clause 7);
- i) extent of fluid leakage and/or diffusion of substances into or out of instruments (see clauses 6 and 7);
- j) the accuracy and stability of instruments with a measuring function (see clauses 7 and 8);
- k) the ability of the instrument or fragment of an instrument to be located by means of an external imaging device (see 11.5).