

Non-active surgical implants — Joint replacement implants — Particular requirements

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British Standard

ICS 11.040.40

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee CH/25, Orthopaedic joint prostheses, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

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Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 9 and a back cover.

Amendments issued since publication

Amd. No.	Date	Text affected

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 July 1998

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Descriptors: Medical equipment, surgical implants, prosthetic devices, specifications, design, surface conditions, materials, manufacturing, sterilization, inspection, packing, information, labelling

English version

Non-active surgical implants — Joint replacement implants — Particular requirements

Implants chirurgicaux non actifs —
Exigences particulières

Nichtaktive chirurgische Implantate —
Implantate zum Gelenkersatz — Besondere
Anforderungen

This European Standard was approved by CEN on 1 January 1998.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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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 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).

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

There are three levels of European Standards dealing with nonactive 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 2 standard and contains requirements that apply to all non-active surgical implants in the family of joint replacement implants.

The level 1 standard 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 1 standard has been published as EN ISO 14630:1997.

Level 3 standards apply to specific types of implants within a family such as knee and hip joints.

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

References can also be found in the annexes of this standard.

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 August 1998, and conflicting national standards shall be withdrawn at the latest by August 1998.

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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