

Biological evaluation of medical devices —

Part 6: Tests for local effects after implantation

The European Standard EN 30993-6:1995 has the status of a
British Standard

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee HCC/26, Biological testing of medical and dental materials and devices, upon which the following bodies were represented:

- Association of British Health-care Industries
- Association of Clinical Pathologists
- Association of Contact Lens Manufacturers
- British Medical Association
- British Orthopaedic Association
- British Plastics Federation
- British Society for Dental Research
- British Surgical Trades Association
- Department of Health
- Department of Trade and Industry (Laboratory of the Government Chemist)
- Disposable Hypodermic and Allied Equipment Manufacturers' Association (UK)
- Electro Medical Trade Association
- Home Office
- Medical Sterile Products Association
- National Blood Transfusion Service
- Royal College of Pathologists
- Royal College of Surgeons of England
- Society for Tissue Viability
- Sterilised Suture Manufacturers' Association
- Surgical Dressings Manufacturers' Association

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National foreword

This British Standard has been prepared by Technical Committee HCC/26 and is the English language version of EN 30993-6:1994 *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation*, published by the European Committee for Standardization (CEN). It is identical with ISO 10993-6:1994 published by the International Organization for Standardization (ISO). EN 30993-6 was produced as a result of international discussions in which the United Kingdom took an active part. It supersedes BS 5736-2:1990 which is withdrawn. Part 1 of BS EN 30993 provides guidance on the selection of tests for the initial assessment of biological hazards in medical devices.

For in vivo tests, attention is drawn to the provisions of the Animals (Scientific Procedures) Act 1986.

Cross-reference

Publication referred to	Corresponding British Standard
EN 30993-1:1992	BS EN 30993 <i>Biological evaluation of medical devices</i> Part 1:1994 <i>Guidance on selection of tests</i>

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 14, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

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English version

Biological evaluation of medical devices — Part 6: Tests for local effects after implantation

(ISO 10993-6:1994)

Evaluation biologique des dispositifs médicaux
Partie 6: Essais concernant les effets locaux
après implantation
(ISO 10993-6:1994)

Biologische Beurteilung von
medizinprodukten —
Teil 6: Prüfungen auf lokale Effekte nach
Implantation
(ISO 10993-6:1994)

This European Standard was approved by CEN on 1994-10-19. 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.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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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 taken over by the Technical Committee CEN/TC 206, Biocompatibility of medical and dental materials and devices, from the work of ISO/TC 194, Biological evaluation of medical devices, of the International Organization for Standardization (ISO).

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 April 1995, and conflicting national standards shall be withdrawn at the latest by April 1995.

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

ISO 10993 consists of the following parts, under the general title *Biological evaluation of medical devices*.

- *Part 1: Guidance on selection of tests;*
- *Part 2: Animal welfare requirements;*
- *Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity;*
- *Part 4: Selection of tests for interactions with blood;*
- *Part 5: Tests for cytotoxicity: in vitro methods;*
- *Part 6: Tests for local effects after implantation;*
- *Part 7: Ethylene oxide sterilization residuals;*
- *Part 8: Clinical investigation;*
- *Part 9: Degradation of materials related to biological testing;*
- *Part 10: Tests for irritation and sensitization;*
- *Part 11: Tests for systemic toxicity;*
- *Part 12: Sample preparation and reference materials.*

Future parts will deal with other relevant aspects of biological testing.

Annex A, Annex B and Annex C of this part of ISO 10993 are for information only.