

Biological evaluation of medical devices —

Part 1: Guidance on selection of tests

The European Standard EN 30993-1:1994 has the status of a
British Standard

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This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on 15 October 1994

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National foreword

This Part of BS EN 30993 has been prepared under the direction of the Health Care Standards Policy Committee and is the English language version of EN 30993-1 *Biological evaluation of medical devices — Part 1: Guidance on selection of tests*, published by the European Committee for Standardization (CEN). It is identical with ISO 10993-1 including Technical Corrigendum 1:1992 published by the International Organization for Standardization (ISO). EN 30993-1 was produced as a result of international discussions in which the United Kingdom took an active part. It supersedes BS 5736-1:1989, which is withdrawn and also partially supersedes BS 5828:1989 which is being revised to remove areas of overlap.

In all cases, users should refer to the guidance given in this Part of BS EN 30993 as the basis for the selection of appropriate biological tests. Where Parts of EN 30993 detailing test methods are not yet available, users may refer to relevant test methods provided in appropriate remaining Parts of BS 5736 or clauses of BS 5828. These methods may be used until corresponding Parts of EN 30993 are adopted.

Other Parts of BS EN 30993 give methods for the tests referred to in this guide. For licensable products, other or additional tests may have to be carried out in order to comply with the conditions of the Medicines Act 1968.

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

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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 12, 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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Descriptors: Medical equipment, surgical equipment, dental equipment, tests, bioassay, selection

English version

Biological evaluation of medical devices — Part 1: Guidance on selection of tests

(ISO 10993-1:1992 + Technical Corrigendum 1:1992)

Essais biologiques des dispositifs médicaux —
Partie 1: Lignes directrices pour le choix des
essais
(ISO 10993-1:1992 + Rectificatif
technique 1:1992)

Biologische Beurteilung von
medizintechnischen Produkten —
Teil 1: Anleitung für die Auswahl von
Prüfungen
(ISO 10993-1:1992 + Technische
Korrektur 1:1992)

This European Standard was approved by CEN on 1993-11-02. 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

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Comité Européen de Normalisation
Europäisches Komitee für Normung

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Foreword

This European Standard is the endorsement of ISO 10993-1:1992 and Technical Corrigendum 1:1992. Endorsement of ISO 10993-1 was recommended by CEN/TC 206, Biocompatibility of medical and dental materials and devices, under whose competence this European Standard will henceforth fall.

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.

Part 1 of ISO 10993 is a combination/harmonization of numerous international and national standards and guidelines. It is intended to be the overall guidance document for the selection of tests enabling evaluation of biological responses relevant to material and device safety.

Annexes A and B of this Part of ISO 10993 are for information only.

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 1994-12 and conflicting national standards shall be withdrawn at the latest by 1995-12.

The standard was approved and in accordance with the CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard:

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