

Biological evaluation of medical devices —

Part 8: Selection and qualification of reference materials for biological tests

The European Standard EN ISO 10993-8:2001 has the status of a
British Standard

ICS 11.040.01; 11.100

National foreword

This British Standard is the official English language version of EN ISO 10993-8:2001. It is identical with ISO 10993-8:2000.

The UK participation in its preparation was entrusted to Technical Committee CH/26, Biological testing of medical and dental materials and devices, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/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

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 August 2001

Summary of pages

This document comprises a front cover, an inside front cover, the EN ISO title page, EN ISO foreword page, ISO title page, pages ii to v, a blank page, pages 1 to 4, an annex ZA page and a back cover.

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English version

Biological evaluation of medical devices - Part 8: Selection and qualification of reference materials for biological tests (ISO 10993-8:2000)

Evaluation biologique des dispositifs médicaux - Partie 8:
Sélection et qualification des matériaux de référence
utilisés pour les essais biologiques (ISO 10993-8:2000)

Biologische Beurteilung von Medizinprodukten - Teil 8:
Auswahl und Eignung von Referenzmaterialien für
biologische Prüfungen (ISO 10993-8:2000)

This European Standard was approved by CEN on 1 September 2000.

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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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

The text of the International Standard ISO 10993-8:2000 has been prepared by Technical Committee ISO/TC 194 "Biological evaluation of medical devices" in collaboration with Technical Committee CEN/TC 206 "Biocompatibility of medical and dental materials and devices", the secretariat of which is held by BSI.

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 March 2001, and conflicting national standards shall be withdrawn at the latest by March 2001.

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.

Endorsement notice

The text of the International Standard ISO 10993-8:2000 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

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Part 8:
Selection and qualification of reference
materials for biological tests**

Évaluation biologique des dispositifs médicaux —

*Partie 8: Sélection et qualification des matériaux de référence utilisés pour
les essais biologiques*



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