National Standards Authority of Ireland

IRISH STANDARD

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ICS 11.100

BIOLOGICAL EVALUATION OF MEDICAL DEVICES

PART 8: SELECTION AND QUALIFICATION OF REFERENCE MATERIALS FOR BIOLOGICAL TESTS

(ISO 10993-8:2000)

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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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPEEN DE NORMALISATION
EUROPAISCHES KOMITEE FÜR NORMUNG

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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of an identical text or by endorsement, at the latest by March 2001, and conflicting national standards shall be withdrawn at the latest by March 2001.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).

Annex ZA (normative)
Normative references to international publications with their relevant European publications

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 edition of the publication referred to applies.

Publication	Year	Title	EN	Year
ISO 10993-12	1996	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials	EN ISO 10993-12	1996