

Biological evaluation of medical devices —

Part 16: Toxicokinetic study design for degradation products and leachables

The European Standard EN ISO 10993-16:1997 has the status of a
British Standard

ICS 11.040.01; 11.060.01; 11.120.01

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National foreword

This British Standard is the English language version of EN ISO 10993-16:1997. It is identical with ISO 10993-16:1997.

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

Attention is drawn to the fact that CEN and CENELEC Standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement these international or European publications 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.

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

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.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN ISO title page, page 2, the ISO title page, pages ii to iv, pages 1 to 8 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.

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 November 1997

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Contents

	Page
National foreword	Inside front cover
Foreword	2
Foreword	iii
Text of ISO 10993-16	1

ICS 11.020.00

Descriptors: See ISO document

English version

Biological evaluation of medical devices —
Part 16: Toxicokinetic study design for
degradation products and leachables

(ISO 10993-16:1997)

Evaluation biologique des dispositifs
médicaux — Partie 16: Conception des études
toxicocinétiques des produits de dégradation
et des substances relargables
(ISO 10993-16:1997)

Biologische Beurteilung von
Medizinprodukten — Teil 16: Entwurf und
Auslegung toxikokinetischer Untersuchungen
hinsichtlich Abbauprodukten und Extrakten
(ISO 10993-16:1997)

This European Standard was approved by CEN on 1997-07-19. 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.

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CEN

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Foreword

The text of the International Standard ISO 10993-16:1997 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 NNI.

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

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 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;*
- *Part 13: Identification and quantification of degradation products from polymers;*
- *Part 14: Identification and quantification of degradation products from ceramics;*
- *Part 15: Identification and quantification of degradation products from coated and uncoated metals and alloys;*
- *Part 16: Toxicokinetic study design for degradation products and leachables;*
- *Part 17: Glutaraldehyde and formaldehyde residues in industrially sterilized medical devices.*

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

Annex A forms an integral part of this part of ISO 10993. Annex B is for information only.

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 10993-16:1997 was approved by CEN as a European Standard without any modification.

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