

Dentistry — Preclinical evaluation of biocompatibility of medical devices used in dentistry — Test methods for dental materials

The European Standard EN ISO 7405:1997 has the status of a
British Standard

ICS 11.060.10; 11.100

NO COPYING WITHOUT BSI PERMISSION EXCEPT AS PERMITTED BY COPYRIGHT LAW



Document Sharing Hub

National foreword

This British Standard is the English language version of EN ISO 7405:1997. It is identical with ISO 7405:1997. It supersedes BS 5828:1989 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/26, Biological testing of medical and dental materials and devices, to Subcommittee CH/26/1, Biological testing for dental materials, 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 subcommittee 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 12 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

© BSI 03-2000

ISBN 0 580 27848 4

Amendments issued since publication

Amd. No.	Date	Comments

Contents

	Page
National foreword	Inside front cover
Foreword	2
Foreword	iv
Text of ISO 7405	1

ICS 11.060.10

Descriptors: See ISO document

English version

**Dentistry — Preclinical evaluation of
biocompatibility of medical devices used in
dentistry — Test methods for dental materials**

(ISO 7405:1997)

Art dentaire — Evaluation préclinique de la
biocompatibilité des dispositifs médicaux
utilisées en art dentaire — Méthodes d'essai des
matériaux dentaires (ISO 7405:1997)

This European Standard was approved by CEN on 1997-04-11. 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.

The European Standards exist 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.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

© 1997 CEN — All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Foreword

The text of the International Standard ISO 7405:1997 has been prepared by Technical Committee ISO/TC 106 “Dentistry” in collaboration with Technical Committee CEN/TC 55 “Dentistry”, the secretariat of which is held by DIN.

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

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 7405:1997 was approved by CEN as a European Standard without any modification.

INTERNATIONAL STANDARD

ISO 7405

First edition
1997-08-15

Dentistry — Preclinical evaluation of biocompatibility of medical devices used in dentistry — Test methods for dental materials

*Art dentaire — Évaluation préclinique de la biocompatibilité des dispositifs
médicaux utilisés en art dentaire — Méthodes d'essai des matériaux
dentaires*



Contents

	Page
Foreword	iii
Introduction	1
1 Scope	1
2 Normative references	1
3 Definitions	1
4 Categorization of medical devices used in dentistry	2
5 Selection of biological evaluation test	2
6 Test procedure specific to dental materials	5
Annex A (informative) Dentine barrier cytotoxicity test	12
Annex B (informative) Acute toxicity testing	12
Annex C (informative) Bibliography	12
Table 1 — Types of test for preclinical evaluation of biocompatibility of dental materials	4

Descriptors: Dentistry, medical equipment, dental equipment, dental materials, tests, biological tests, determination, biocompatibility.