

Implants for surgery — Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical devices

ICS 11.040.40

National foreword

This British Standard reproduces verbatim ISO 16428:2005 and implements it as the UK national standard.

The UK participation in its preparation was entrusted by Technical Committee CH/150, Implants for surgery, to Subcommittee CH/150/1, Materials for surgical implants, 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 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

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

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its 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, the ISO title page, pages ii to v, a blank page, pages 1 to 8, an inside back cover and a back cover.

The BSI copyright notice displayed in this document indicates when the document was last issued.

Amendments issued since publication

Amd. No.	Date	Comments

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 10 June 2005

© BSI 10 June 2005

INTERNATIONAL STANDARD

ISO
16428

First edition
2005-04-01

Implants for surgery — Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical devices

*Implants chirurgicaux — Solutions d'essai et conditions
environnementales pour les essais statiques et dynamiques de
corrosion sur les matériaux et dispositifs médicaux implantables*



Reference number
ISO 16428:2005(E)

AVA **Documents**
Document Sharing Hub

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Significance and application	2
4.1 Significance of test solution	2
4.2 Application	2
5 Environmental testing conditions	3
5.1 Test solution	3
5.2 Testing temperature	3
5.3 pH value	3
5.4 Aeration	3
5.5 Volume of test solution	3
5.6 Circulation of the solution	4
5.7 Test chamber	4
6 Test specimens	4
7 Evaluation and reporting	4
7.1 Evaluation of test results	4
7.2 Test report	4
Annex A (informative) Additional test solutions	6
Annex B (informative) Considerations for surface preparation and test evaluation	7
Bibliography	8

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 16428 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.