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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)

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Published in Switzerland

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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

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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.

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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*.

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Introduction

In many instances testing of medical devices and materials in a physiological environment is highly desirable for scientific purposes and development work as well as for the assessment of the performance of surgical implants and devices. The application of original physiological fluids is often difficult because of the rapid deterioration of such media.

The application of artificial media is common, but there is the disadvantage that the compositions vary widely and testing results are often not comparable.

This International Standard specifies basic reproducible environmental conditions using a test fluid of isotonic sodium chloride (NaCl) solution. This solution is appropriate because it is used for injections and irrigation in surgery and has an ion content similar to that of human body fluids. Of particular importance are the chloride (Cl^-) ions because the corrosion resistance of most metals is very sensitive to them. Correspondingly, the isotonic NaCl solution is already widely used in the testing of medical devices.