SLOVENSKI STANDARD

SIST EN ISO 10993-12:2008

01-april-2008

Nadomeġ a:

SIST EN ISO 10993-12:2005

Bioloġko ovrednotenje medicinskih pripomoļ kov - 12. del: Priprava vzorcev in referenļ ni materiali (ISO 10993-12:2007)

Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2007)

Biologische Beurteilung von Medizinprodukten - Teil 12: Proben-vorbereitung und Referenzmaterialien (ISO 10993-12:2007)

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Evaluation biologique des dispositifs médicaux - Partie 12: Préparation des échantillons et des matériaux de référence (ISO 10993-12:2007)

SIST EN ISO 10993-12:2008
https://standards.iteh.ai/catalog/standards/sist/d657436b-1aac-4f4c-b371-423da67d2031/sist-en-iso-10993-12-2008

Ta slovenski standard je istoveten z: **EN ISO 10993-12:2007**

ICS:

11.100.20

SIST EN ISO 10993-12:2008 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 10993-12:2008
https://standards.iteh.ai/catalog/standards/sist/d657436b-1aac-4f4c-b371-423da67d2031/sist-en-iso-10993-12-2008

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10993-12

November 2007

ICS 11.100.20

Supersedes EN ISO 10993-12:2004

English Version

Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2007)

Évaluation biologique des dispositifs médicaux - Partie 12: Préparation des échantillons et matériaux de référence (ISO 10993-12:2007)

Biologische Beurteilung von Medizinprodukten - Teil 12: Proben-vorbereitung und Referenzmaterialien (ISO 10993-12:2007)

This European Standard was approved by CEN on 30 September 2007.

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 CEN Management Centre or to any CEN member.

This European Standard exists 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 CEN Management Centre has the same status as the official versions.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

SIST EN ISO 10993-12:2008
https://standards.iteh.ai/catalog/standards/sist/d657436b-1aac-4f4c-b371-423da67d2031/sist-en-iso-10993-12-2008

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

© 2007 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Contents

Page

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN ISO 10993-12:2008
https://standards.iteh.ai/catalog/standards/sist/d657436b-1aac-4f4c-b371-423da67d2031/sist-en-iso-10993-12-2008

Foreword

This document (EN ISO 10993-12:2007) has been prepared by Technical Committee ISO/TC 194 "Biological evaluation of medical devices" in collaboration with Technical Committee CEN/TC 206 “Biological evaluation of medical devices” the secretariat of which is held by NEN.

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 May 2008, and conflicting national standards shall be withdrawn at the latest by May 2008.

This document supersedes EN ISO 10993-12:2004.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive(s).

For relationship with EC Directive(s), see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Endorsement notice

SIST EN ISO 10993-12:2008
https://standards.iteh.ai/catalog/standards/sist/d6574366-1aac-4fbc-b371-423da67d2031/sist-en-iso-10993-12-2008

The text of ISO 10993-12:2007 has been approved by CEN as a EN ISO 10993-12:2007 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directives 93/42/EEC on medical devices and 90/385/EEC on active implantable medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directives 93/42/EEC on medical devices and 90/385/EEC on active implantable medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this International Standard and Directives 93/42/EEC on medical devices and 90/385/EEC on active implantable medical devices

Clause(s)/sub-clause(s) of this International Standard	Essential Requirements (ERs) of Directives 93/42/EEC and 90/385/EEC	Qualifying remarks/Notes
1, 7, 8, 9, 10	93/42/EEC: Annex I, 11.7	
1, 7, 8, 9, 10	90/385/EEC: Annex I.1 and 11.9	

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN ISO 10993-12:2008
https://standards.iteh.ai/catalog/standards/sist/d657436b-1aac-4f4c-b371-423da67d2031/sist-en-iso-10993-12-2008

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 10993-12

Third edition
2007-11-15

Biological evaluation of medical devices —

Part 12: Sample preparation and reference materials

Évaluation biologique des dispositifs médicaux —

Partie 12: Préparation des échantillons et matériaux de référence

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN ISO 10993-12:2008
https://standards.iteh.ai/catalog/standards/sist/d657436b-1aac-4f4c-b371-423da67d2031/sist-en-iso-10993-12-2008

Reference number
ISO 10993-12:2007(E)

© ISO 2007

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 10993-12:2008
https://standards.iteh.ai/catalog/standards/sist/d657436b-1aac-4f4c-b371-423da67d2031/sist-en-iso-10993-12-2008

COPYRIGHT PROTECTED DOCUMENT

© ISO 2007

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

 © ISO 2007 – All rights reserved

Contents

Page

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN ISO 10993-12:2008
https://standards.iteh.ai/catalog/standards/sist/d657436b-1aac-4f4c-b371-423da67d2031/sist-en-iso-10993-12-2008

© ISO 2007 – All rights reserved

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 10993-12 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

This third edition cancels and replaces the second edition (ISO 10993-12:2002), which has been technically revised.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 10993 consists of the following parts, under the general title *Biological evaluation of medical devices*:

SIST EN ISO 10993-12:2008
https://standards.iteh.ai/catalog/standards/sist/d657436b-1aac-4f4c-b371-423da67d2031/sist-en-iso-10993-12-2008

— *Part 1: Evaluation and testing*

— *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* in vitro *cytotoxicity*

— *Part 6: Tests for local effects after implantation*

— *Part 7: Ethylene oxide sterilization residuals*

— *Part 9: Framework for identification and quantification of potential degradation products*

— *Part 10: Tests for irritation and delayed-type hypersensitivity*

— *Part 11: Tests for systemic toxicity*

— *Part 12: Sample preparation and reference materials*

— *Part 13: Identification and quantification of degradation products from polymeric medical devices*

— *Part 14: Identification and quantification of degradation products from ceramics*

— *Part 15: Identification and quantification of degradation products from metals and alloys*

© ISO 2007 – All rights reserved

— *Part 16: Toxicokinetic study design for degradation products and leachables*

— *Part 17: Establishment of allowable limits for leachable substances*

— *Part 18: Chemical characterization of materials*

— *Part 19: Physico-chemical, morphological and topographical characterization of materials* [TS]

— *Part 20: Principles and methods for immunotoxicology testing of medical devices* [TS]

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN ISO 10993-12:2008
https://standards.iteh.ai/catalog/standards/sist/d657436b-1aac-4f4c-b371-423da67d2031/sist-en-iso-10993-12-2008

© ISO 2007 – All rights reserved