



SLOVENSKI STANDARD
SIST EN ISO 10993-14:2009
01-julij-2009

BUXca Yý U
SIST EN ISO 10993-14:2002

6]c`cý_c`cj fYXbchYb^a YX]V]bg_]\`df]dca c _cj`!`%`"XY.`DfYdcnbUj Ub^]b
i [chUj`^Ub^_c`]]bYfUh[fUXb]\`dfcXi _hcj`n`_YfUa]_YfIGC`%\$-`!`%`.&\$%&

Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics (ISO 10993-14:2001)

Biologische Beurteilung von Medizinprodukten - Teil 14: Qualitativer und quantitativer Nachweis von keramischen Abbauprodukten (ISO 10993-14:2001)

Evaluation biologique des dispositifs médicaux - Partie 14 : Identification et quantification des produits de dégradation des céramiques (ISO 10993-14:2001)

Ta slovenski standard je istoveten z: EN ISO 10993-14:2009

ICS:

11.100.20 Óä [[z\ [Á ç!^â} [c\} ¢ Biological evaluation of
{ ^ääã • \ã@ iã [[{ [\ [ç medical devices

SIST EN ISO 10993-14:2009 en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 10993-14:2009](https://standards.iteh.ai/catalog/standards/sist/08bc5f3b-e512-4c5a-8b41-6546ded44d6d/sist-en-iso-10993-14-2009)

<https://standards.iteh.ai/catalog/standards/sist/08bc5f3b-e512-4c5a-8b41-6546ded44d6d/sist-en-iso-10993-14-2009>

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 10993-14

April 2009

ICS 11.100.20

Supersedes EN ISO 10993-14:2001

English Version

**Biological evaluation of medical devices - Part 14: Identification
and quantification of degradation products from ceramics (ISO
10993-14:2001)**

Évaluation biologique des dispositifs médicaux - Partie 14:
Identification et quantification des produits de dégradation
des céramiques (ISO 10993-14:2001)

Biologische Beurteilung von Medizinprodukten - Teil 14:
Qualitativer und quantitativer Nachweis von keramischen
Abbauprodukten (ISO 10993-14:2001)

This European Standard was approved by CEN on 12 April 2009.

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.

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.

<https://standards.iteh.ai/catalog/standards/sist/086c515b-e512-4c5a-8b41-6546ded44d6d/sist-en-iso-10993-14-2009>



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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents	Page
Foreword	3
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices	4

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 10993-14:2009](https://standards.iteh.ai/catalog/standards/sist/08bc5f3b-e512-4c5a-8b41-6546ded44d6d/sist-en-iso-10993-14-2009)
<https://standards.iteh.ai/catalog/standards/sist/08bc5f3b-e512-4c5a-8b41-6546ded44d6d/sist-en-iso-10993-14-2009>

Foreword

The text of ISO 10993-14:2001 has been prepared by Technical Committee ISO/TC 194 "Biological evaluation of medical devices" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 10993-14:2009 by 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 October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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

This document supersedes EN ISO 10993-14:2001.

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 EU Directive 93/42/EEC on Medical Devices.

For relationship with the EU Directive, 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.

Endorsement notice

The text of ISO 10993-14:2001 has been approved by CEN as a EN ISO 10993-14:2009 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on 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 Directive 93/42/EEC on 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 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 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4, 5, 6	Annex I: 7.1, 7.2, 7.5	

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

INTERNATIONAL
STANDARD

ISO
10993-14

First edition
2001-11-15

**Biological evaluation of medical devices —
Part 14:
Identification and quantification of
degradation products from ceramics**

*Évaluation biologique des dispositifs médicaux —
Partie 14: Identification et quantification des produits de dégradation des
céramiques*

[SIST EN ISO 10993-14:2009
https://standards.iteh.ai/catalog/standards/sist/08bc5f3b-e512-4c5a-8b41-6546ded44d6d/sist-en-iso-10993-14-2009](https://standards.iteh.ai/catalog/standards/sist/08bc5f3b-e512-4c5a-8b41-6546ded44d6d/sist-en-iso-10993-14-2009)



Reference number
ISO 10993-14:2001(E)

© ISO 2001

ISO 10993-14:2001(E)**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 10993-14:2009](https://standards.iteh.ai/catalog/standards/sist/08bc5f3b-e512-4c5a-8b41-6546ded44d6d/sist-en-iso-10993-14-2009)

<https://standards.iteh.ai/catalog/standards/sist/08bc5f3b-e512-4c5a-8b41-6546ded44d6d/sist-en-iso-10993-14-2009>

© ISO 2001

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.ch
Web www.iso.ch

Printed in Switzerland

Contents

	Page
Foreword.....	iv
Introduction.....	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Test procedures	2
4.1 Principle.....	2
4.2 Testing of dental devices.....	2
4.3 General testing techniques.....	3
4.4 Extreme solution test	4
4.5 Simulation solution test	6
5 Analysis of filtrate.....	9
5.1 General.....	9
5.2 Choice of chemicals or elements to be analysed.....	9
5.3 Sensitivity of the analysis method.....	9
6 Test report	9
Bibliography	11

[SIST EN ISO 10993-14:2009](https://standards.iteh.ai/catalog/standards/sist/08bc5f3b-e512-4c5a-8b41-6546ded44d6d/sist-en-iso-10993-14-2009)
<https://standards.iteh.ai/catalog/standards/sist/08bc5f3b-e512-4c5a-8b41-6546ded44d6d/sist-en-iso-10993-14-2009>

ISO 10993-14:2001(E)

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 3.

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 part of ISO 10993 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 10993-14 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

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

- 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 8: Selection and qualification of reference materials for biological tests
- 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
- Part 16: Toxicokinetic study design for degradation products and leachables

- *Part 17: Establishment of allowable limits for leachable substances using health-based risk assessment*
- *Part 18: Chemical characterization of materials*

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 10993-14:2009](https://standards.iteh.ai/catalog/standards/sist/08bc5f3b-e512-4c5a-8b41-6546ded44d6d/sist-en-iso-10993-14-2009)

<https://standards.iteh.ai/catalog/standards/sist/08bc5f3b-e512-4c5a-8b41-6546ded44d6d/sist-en-iso-10993-14-2009>