



SLOVENSKI STANDARD  
SIST EN ISO 10993-18:2005  
01-september-2005

Biological evaluation of medical devices - Part 18: Chemical characterization of materials (ISO 10993-18:2005)

Biologische Beurteilung von Medizinprodukten - Teil 18: Chemische Charakterisierung von Werkstoffen (ISO 10993-18:2005)

Evaluation biologique des dispositifs médicaux - Partie 18: Caractérisation chimique des matériaux (ISO 10993-18:2005)

iTeh STANDARD PREVIEW

(standards.iteh.ai)

Evaluation biologique des dispositifs médicaux - Partie 18: Caractérisation chimique des matériaux (ISO 10993-18:2005)

SIST EN ISO 10993-18:2005

<https://standards.iteh.ai/catalog/standards/sist/808a7b7d-82a4-4137-8a9a-4c5aae5d403d/sist-en-iso-10993-18-2005>

Ta slovenski standard je istoveten z: EN ISO 10993-18:2005

ICS:

11.100.20      Óä || z\ [ Á ç!^â} [ c^} b      Biological evaluation of  
{ ^âãä • \ã@ |ä [ { [ \ [ ç      medical devices

SIST EN ISO 10993-18:2005

en

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

SIST EN ISO 10993-18:2005

<https://standards.iteh.ai/catalog/standards/sist/808a7b7d-82a4-4137-8a9a-4c3aae5d403d/sist-en-iso-10993-18-2005>

ICS 11.100.20

English Version

Biological evaluation of medical devices - Part 18: Chemical  
characterization of materials (ISO 10993-18:2005)

Evaluation biologique des dispositifs médicaux - Partie 18:  
Caractérisation chimique des matériaux (ISO 10993-  
18:2005)

Biologische Beurteilung von Medizinprodukten - Teil 18:  
Chemische Charakterisierung von Werkstoffen (ISO  
10993-18:2005)

This European Standard was approved by CEN on 6 June 2005.

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.

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 Central Secretariat has the same status as the official versions.

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

[SIST EN ISO 10993-18:2005](https://standards.iteh.ai/catalog/standards/sist/en-iso-10993-18-2005)

<https://standards.iteh.ai/catalog/standards/sist/808a7b7d-82a4-4137-8a9a-4c3aae5d403d/sist-en-iso-10993-18-2005>



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

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

## Foreword

This document (EN ISO 10993-18:2005) has been prepared by Technical Committee CEN/TC 206 "Biocompatibility of medical and dental materials and devices", the secretariat of which is held by NEN, in collaboration with Technical Committee ISO/TC 194 "Biological evaluation of medical devices".

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 January 2006, and conflicting national standards shall be withdrawn at the latest by January 2006.

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(s).

For relationship with EU 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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

(standards.iteh.ai)

### Endorsement notice

SIST EN ISO 10993-18:2005

The text of ISO 10993-18:2005 has been approved by CEN as EN ISO 10993-18:2005 without any modifications.

<https://standards.iteh.ai/catalog/standards/sist/6061767e-6214-4197-b23d-4c3aae5d403d/sist-en-iso-10993-18-2005>

**ANNEX ZA**  
(informative)

**Relationship between this European Standard and the Essential Requirements of EU Directive 93/42 EEC**

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.

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 normative 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.

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

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

SIST EN ISO 10993-18:2005

<https://standards.iteh.ai/catalog/standards/sist/808a7b7d-82a4-4137-8a9a-4c3aae5d403d/sist-en-iso-10993-18-2005>

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

SIST EN ISO 10993-18:2005

<https://standards.iteh.ai/catalog/standards/sist/808a7b7d-82a4-4137-8a9a-4c3aae5d403d/sist-en-iso-10993-18-2005>

---

---

**Biological evaluation of medical  
devices —**

**Part 18:  
Chemical characterization of materials**

*Évaluation biologique des dispositifs médicaux —  
Partie 18: Caractérisation chimique des matériaux*  
**(standards.iteh.ai)**

SIST EN ISO 10993-18:2005

<https://standards.iteh.ai/catalog/standards/sist/808a7b7d-82a4-4137-8a9a-4c3aae5d403d/sist-en-iso-10993-18-2005>



**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 10993-18:2005](https://standards.iteh.ai/catalog/standards/sist/808a7b7d-82a4-4137-8a9a-4c3aae5d403d/sist-en-iso-10993-18-2005)

<https://standards.iteh.ai/catalog/standards/sist/808a7b7d-82a4-4137-8a9a-4c3aae5d403d/sist-en-iso-10993-18-2005>

© ISO 2005

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](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland



# Contents

Page

Foreword.....	iv
Introduction .....	vi
<b>1 Scope .....</b>	<b>1</b>
<b>2 Normative references .....</b>	<b>1</b>
<b>3 Terms and definitions.....</b>	<b>2</b>
<b>4 Symbols and abbreviated terms .....</b>	<b>3</b>
<b>5 General principles.....</b>	<b>3</b>
<b>6 Characterization procedure .....</b>	<b>4</b>
6.1 General.....	4
6.2 Step 1 — Qualitative information .....	5
6.3 Step 2 — Material equivalence .....	5
6.4 Step 3 — Quantitative information.....	5
6.5 Step 4 — Quantitative risk assessment.....	5
6.6 Step 5 — Estimated clinical exposure to chemicals present.....	6
<b>7 Chemical characterization parameters and methods .....</b>	<b>6</b>
7.1 General.....	6
7.2 Polymers.....	7
7.3 Metals and alloys .....	8
7.4 Ceramics.....	8
7.5 Natural macromolecules.....	9
<b>8 Reporting of data obtained.....</b>	<b>10</b>
<b>Annex A (normative) Flowchart summarizing the stepwise generation of chemical characterization data for use in toxicological risk assessment .....</b>	<b>11</b>
<b>Annex B (informative) Information sources for chemical characterization .....</b>	<b>13</b>
<b>Annex C (informative) Principles for judging toxicological equivalency .....</b>	<b>16</b>
<b>Bibliography .....</b>	<b>17</b>

## 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 10993-18 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 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*

— *Part 18: Chemical characterization of materials*

The following parts are under preparation:

— *Part 19: Physico-chemical, mechanical and morphological characterization*

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

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

For the purposes of this part of ISO 10993, the CEN annex regarding fulfilment of European Council Directives has been removed.

## iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN ISO 10993-18:2005

<https://standards.iteh.ai/catalog/standards/sist/808a7b7d-82a4-4137-8a9a-4c3aae5d403d/sist-en-iso-10993-18-2005>