

# SLOVENSKI STANDARD

## kSIST prEN ISO 10993-4:2009

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Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002, including Amd 1:2006)

Biologische Beurteilung von Medizinprodukten - Teil 4: Auswahl von Prüfungen zur Wechselwirkung mit Blut (ISO 10993-4:2002, einschließlich Änderung 1:2006)

Évaluation biologique des dispositifs médicaux - Partie 4 : Choix des essais concernant les interactions avec le sang (ISO 10993-4:2002, Amd 1:2006 inclus)

**Ta slovenski standard je istoveten z: prEN ISO 10993-4**

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**kSIST prEN ISO 10993-4:2009**

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**FINAL DRAFT**  
**prEN ISO 10993-4**

November 2008

ICS 11.100.20

Will supersede EN ISO 10993-4:2002

English Version

**Biological evaluation of medical devices - Part 4: Selection of  
tests for interactions with blood (ISO 10993-4:2002, including  
Amd 1:2006)**

Évaluation biologique des dispositifs médicaux - Partie 4:  
Choix des essais pour les interactions avec le sang (ISO  
10993-4:2002, Amd 1:2006 inclus)

Biologische Beurteilung von Medizinprodukten - Teil 4:  
Auswahl von Prüfungen zur Wechselwirkung mit Blut (ISO  
10993-4:2002, einschließlich Änderung 1:2006)

This draft European Standard is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 206.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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.

**Warning** : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
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## Foreword

The text of ISO 10993-4:2002, including Amd 1:2006 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 prEN ISO 10993-4:2008 by Technical Committee CEN/TC 206 “Biological evaluation of medical devices” the secretariat of which is held by NEN.

This document is currently submitted to the Unique Acceptance Procedure.

This document will supersede EN ISO 10993-4:2002.

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 Directives.

For relationship with EC Directives, see informative Annex ZA et ZB which are integral part of this document.

### Endorsement notice

The text of ISO 10993-4:2002, including Amd 1:2006 has been approved by CEN as a prEN ISO 10993-4:2008 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
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.

## Annex ZB (informative)

### Relationship between this European Standard and the Essential Requirements of EU Directive 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 Directive 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 ZB 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 ZB — Correspondence between this European Standard and Directive 90/385/EEC on active implantable medical devices**

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 90/385/EEC	Qualifying remarks/Notes
6	Annex I : 9	
6	7.1 of Annex I and Annex II of 93/42/EEC  I.9 of Annex I of 90/385/EEC	
6.1.10	18 of 86/609/EEC	
A.1	7.1 of Annex I and Annex II of 93/42/EEC  I.9 of Annex I of 90/385/EEC	

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

