



**SLOVENSKI STANDARD**  
**kSIST prEN ISO 10993-9:2009**  
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Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:1999)

Biologische Beurteilung von Medizinprodukten - Teil 9: Rahmen zur Identifizierung und Quantifizierung von möglichen Abbauprodukten (ISO 10993-9:1999)

Évaluation biologique des dispositifs médicaux - Partie 9: Cadre pour l'identification et la quantification des produits potentiels de dégradation (ISO 10993-9:1999)

**Ta slovenski standard je istoveten z: prEN ISO 10993-9**

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**kSIST prEN ISO 10993-9:2009**                      **en**



EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**FINAL DRAFT**  
**prEN ISO 10993-9**

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Will supersede EN ISO 10993-9:1999

English Version

**Biological evaluation of medical devices - Part 9: Framework for  
identification and quantification of potential degradation products  
(ISO 10993-9:1999)**

Évaluation biologique des dispositifs médicaux - Partie 9:  
Cadre pour l'identification et la quantification des produits  
potentiels de dégradation (ISO 10993-9:1999)

Biologische Beurteilung von Medizinprodukten - Teil 9:  
Rahmen zur Identifizierung und Quantifizierung von  
möglichen Abbauprodukten (ISO 10993-9:1999)

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.

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**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  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

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## Foreword

The text of ISO 10993-9:1999 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 10993-9:2008 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 10993-9:1999.

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 Directives 93/42/EEC on Medical Devices and 90/385/EEC on Active Implantable Medical Devices.

For relationship with EU Directives, see informative Annex ZA and ZB, which is an integral part of this document.

### Endorsement notice

The text of ISO 10993-9:1999 has been approved by CEN as a prEN ISO 10993-9:2008 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
4, 5, & Annex A	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
4, 5, Annex A	Annex I : 9	The test methods do not include pass/fail criteria

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

