



SLOVENSKI STANDARD SIST EN ISO 10993-1:2009

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Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:2003)

Biologische Beurteilung von Medizinprodukten Teil 1: Beurteilung und Prüfungen (ISO 10993-1:2003)

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Evaluation biologique des dispositifs médicaux Partie 1: Evaluation et essais (ISO 10993-1:2003)

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Ta slovenski standard je istoveten z: EN ISO 10993-1:2009

ICS:

11.100.20 Óä [[z [Á ç!^â} [c } b Biological evaluation of
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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 10993-1

June 2009

ICS 11.100.20

Supersedes EN ISO 10993-1:2003

English Version

Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:2003)

Évaluation biologique des dispositifs médicaux - Partie 1:
Evaluation et essais (ISO 10993-1:2003)

Biologische Beurteilung von Medizinprodukten Teil 1:
Beurteilung und Prüfung (ISO 10993-1:2003)

This European Standard was approved by CEN on 23 May 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.

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Foreword

The text of ISO 10993-1:2003 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 10993-1:2009 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 December 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 10993-1:2003.

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.

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 10993-1:2003 has been approved by CEN as a EN ISO 10993-1:2009 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
3, 4, 5, 6, 7	Annex I 7.1, 7.2, 7.5	The presumption of conformity depends on applying the other parts of the EN ISO 10993 series that are relevant

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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
3, 4, 5, 6, 7	Annex I. 9	The presumption of conformity depends on applying the other parts of the EN ISO 10993 series that are relevant

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INTERNATIONAL STANDARD

ISO 10993-1

Third edition
2003-08-01

Biological evaluation of medical devices —

Part 1: Evaluation and testing

*Évaluation biologique des dispositifs médicaux —
Partie 1: Évaluation et essais*
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