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SLOVENSKI STANDARD
SIST EN ISO 10993-1:2010

01-januar-2010

Nadomeġļa:
SIST EN ISO 10993-1:2009

Biologġko ovrednotenje medicinskih pripomoļkov - 1. del: Ocena in preskuġanje znotraj procesa obvladovanja tveganja (ISO 10993-1:2009)

Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)

Biologische Beurteilung von Medizinprodukten - Teil 1: Beurteilung und Prüfungen im Rahmen eines Risikomanagementsystems (ISO 10993-1:2009)

Évaluation biologique des dispositifs médicaux - Partie 1: Évaluation et essais au sein d'un processus de gestion du risque (ISO 10993-1:2009)

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

ICS:

11.100.20	Biologġko ovrednotenje medicinskih pripomoļkov	Biological evaluation of medical devices

SIST EN ISO 10993-1:2010 **en**

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 10993-1

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English Version

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Évaluation biologique des dispositifs médicaux - Partie 1: Évaluation et essais au sein d'un processus de gestion du risque (ISO 10993-1:2009)

Biologische Beurteilung von Medizinprodukten - Teil 1: Beurteilung und Prüfungen im Rahmen eines Risikomanagementsystems (ISO 10993-1:2009)

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Foreword

This document (EN ISO 10993-1:2009) has been prepared by Technical Committee ISO/TC 194 "Biological evaluation of medical devices" in collaboration with 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of an identical text or by endorsement, at the latest by April 2010, and conflicting national standards shall be withdrawn at the latest by April 2010.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 10993-1:2009, June.

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.

For relationship with EU Directives, see informative Annex ZA and ZB, which are integral parts of this document.

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The text of ISO 10993-1:2009 has been approved by CEN as a EN ISO 10993-1:2009 without any modification.

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Annex ZA
(informative)

Relationship between this International Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical devices

This International 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 International Standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this International Standard given in Table ZA.1 confers, within the limits of the scope of this Intenational Standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this International Standard and Directive 93/42/EEC on Medical devices

Clause(s)/subclause(s) of this International Standard	Essential Requirements (ERs) of Directive 93/42/EEC on Medical devices	Qualifying remarks/notes
4, 5, 6, 7	Annex I: 7.1, 7.2 and 7.5	

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

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Annex ZB
(informative)

Relationship between this International Standard and the Essential Requirements of EU Directive 90/385/EEC on Active Implantable Medical Devices

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Table ZB.1 — Correspondence between this European Standard and Directive 90/385/EEC on Active Implantable Medical Devices

Clause(s)/subclause(s) of this International Standard	Essential Requirements (ERs) of Directive 90/385/EEC on Active Implantable Medical Devices	Qualifying remarks/notes
4, 5, 6, 7	Annex I, Indents 1 and 2 of Clause 9 only	

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