SLOVENSKI STANDARD
SIST EN ISO 10993-1:2010/AC:2010

01-november-2010

Biološko ovrednotenje medicinskih pripomočkov - 1. del: Ocena in preskušanje znotraj procesa obvladovanja tveganja - Popravek 1 (ISO 10993-1:2009/Cor 1:2010)

Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process - Technical Corrigendum 1 (ISO 10993-1:2009/Cor 1:2010)

Biologische Beurteilung von Medizinprodukten - Teil 1: Beurteilung und Prüfung im Rahmen eines Risikomanagementverfahrens (ISO 10993-1:2009/Cor 1:2010)

Évaluation biologique des dispositifs médicaux - Partie 1: Évaluation et essais au sein d'un processus de gestion du risque - Rectificatif technique 1 (ISO 10993-1:2009/Cor 1:2010)

Ta slovenski standard je istoveten z: EN ISO 10993-1:2009/AC:2010

ICS:

11.100.20	Biološko ovrednotenje medicinskih pripomočkov	Biological evaluation of medical devices

SIST EN ISO 10993-1:2010/AC:2010 en

EUROPEAN STANDARD

NORME EUROPÉENNE

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June 2010
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Version Française
Deutsche Fassung

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This corrigendum becomes effective on 15 June 2010 for incorporation in the three official language versions of the EN.

Ce corrigendum prendra effet le 15 juin 2010 pour incorporation dans les trois versions linguistiques officielles de la EN.

Die Berichtigung tritt am 15.Juni 2010 zur Einarbeitung in die drei offiziellen Sprachfassungen der EN in Kraft.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 10993-1:2009/AC:2010) 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.

Endorsement notice

The text of ISO 10993-1:2009/Cor 1:2010 has been approved by CEN as a EN ISO 10993-1:2009/AC:2010 without any modification.

INTERNATIONAL STANDARD ISO 10993-1:2009
TECHNICAL CORRIGENDUM 1

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INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Biological evaluation of medical devices —

Part 1:
Evaluation and testing within a risk management process

TECHNICAL CORRIGENDUM 1

Évaluation biologique des dispositifs médicaux —

Partie 1: Évaluation et essais au sein d'un processus de gestion du risque

RECTIFICATIF TECHNIQUE 1

Technical Corrigendum 1 to ISO 10993-1:2009 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

Page 5, Figure 1

On the top left-hand side of the flowchart, and to the right of the rhombus indicating “Is there either direct or indirect contact?”, replace “1.0” with “Clause 1”.

On the lower left-hand side of the flowchart, and to the top right of the rectangle indicating “Perform further evaluation of device ... and type and duration of contact”, replace “7.0” with “Clause 7”.

On the lower right-hand side of the flowchart, replace the text in the bottom right rectangle with “Perform toxicological risk assessment (Annex B)”.

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