POLSKI KOMITET NORMALIZACYJNY

# POPRAWKA do POLSKIEJ NORMY

ICS 11.100.20;

# PN-EN ISO 10993-1:2010/AC

**grudzień 2010**

**Wprowadza**
EN ISO 10993-1:2009/AC:2010, IDT
ISO 10993-1:2009/AC1:2010, IDT

**Dotyczy**
PN-EN ISO 10993-1:2010

## Biologiczna ocena wyrobów medycznych -- Część 1: Ocena i badanie w procesie zarządzania ryzykiem

Na wniosek Komitetu Technicznego nr 247
ds. Materiałów Medycznych i Biomateriałów
**Poprawka do Normy Europejskiej EN ISO 10993-1:2009/AC: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)**
ma status Poprawki do Polskiej Normy

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN ISO 10993-1:2009/AC

June 2010
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Juni 2010

**ICS** 11.100.20

English version
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Deutsche Fassung

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)

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)

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

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

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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

Published 2010-06-15

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)”.

**ICS 11.100.20** **Ref. No. ISO 10993-1:2009/Cor.1:2010(E)**

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