



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)”.