



**INTERNATIONAL STANDARD ISO 10993-7:2008**  
TECHNICAL CORRIGENDUM 1

Published 2009-11-15

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

## **Biological evaluation of medical devices —**

### **Part 7: Ethylene oxide sterilization residuals**

#### **TECHNICAL CORRIGENDUM 1**

*Évaluation biologique des dispositifs médicaux —*

*Partie 7: Résidus de stérilisation à l'oxyde d'éthylène*

*RECTIFICATIF TECHNIQUE 1*

Technical Corrigendum 1 to ISO 10993-7:2008 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

---

*Page iv, Foreword*

Correct the title of Part 1 to read as follows:

— *Part 1: Evaluation and testing within a risk management process*

*Page 10, 5.3 Procedure for product release using residue dissipation curves*

Second paragraph, second sentence should read:

Dissipation of EO from most materials and devices follows first-order kinetics, i.e.  $(\ln[\text{EO}]) \propto (\text{time after sterilization})$ .

**Pour plus d'infos, merci de nous contacter.**

**Association Sénégalaise de Normalisation**

4 Avenue Jean Jaurès, Immeuble El Hadj Omar DIA, 6 ème Etage  
Dakar - SENEGAL

**Tel: +221 33 829 58 25**

**Email: [asn@asn.sn](mailto:asn@asn.sn)**