



**INTERNATIONAL STANDARD ISO 10993-7:2008**  
**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 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*.

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*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.  $(\ln[\text{EO}]) \propto$  (time after sterilization).

Page 13

Equation (A.5) should read as follows:

$$\sigma^2 = \frac{\left( \sum y^2 - \frac{(\sum y)^2}{n} \right) - S \times \left( \sum xy - \frac{(\sum x \sum y)}{n} \right)}{n - 2} \quad (\text{A.5})$$

Equation (A.6) should read as follows:

$$\lambda = \frac{\sum y}{n} \quad (\text{A.6})$$

Page 29, F.2.2 Intraocular lens limits

First paragraph, third sentence should read as follows:

This is necessary to prevent documented irritation responses of EO to ocular tissue (see References [44], [117], [118], [119] and [167]).

Second paragraph, third sentence should read as follows:

In such cases, References [44], [117], [118] and [119] indicate that the level of ECH that results in ocular toxicity is about four times greater than the corresponding EO level.

Page 30, F.2.5 Devices used in cardiopulmonary bypass procedures

First paragraph, delete the following sentences:

At this UTF, the allowable limit would increase to 21 mg EO. The EO limit reflects manufacturers' current ability to remove EO from these rather large devices.

Page 63, J.1.1

Footnote 9) should read as follows:

1 mmHg = 133,322 Pa or 760 mmHg = 101,325 kPa.