



# Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization

## TECHNICAL CORRIGENDUM 1

*Stérilisation des dispositifs médicaux — Prescriptions pour la validation et le contrôle de routine — Stérilisation par irradiation*

RECTIFICATIF TECHNIQUE 1

Technical Corrigendum 1 to International Standard ISO 11137:1995 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

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### **B.3.4.2.2.3 Stage 3: Perform verification dose experiment**

(For Method 2A) Replace the last two sentences of the first paragraph with the following text:

“The actual dose may vary from the D\* kGy dose by + 1,0 kGy or + 10 %, whichever is greater. If the delivered dose is less than 90 % of the D\* kGy dose, the verification dose experiment may be repeated.”

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### **B.3.4.2.4.3 Stage 3: Perform verification dose experiment**

(For Method 2B) Replace the last two sentences of the first paragraph with the following text.

“The actual dose may vary from the D\* kGy dose by + 1,0 kGy or + 10 %, whichever is greater. If the delivered dose is less than 90 % of the D\* kGy dose, the verification dose experiment may be repeated.”