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**Sterilization of health care products —  
Radiation —**

**Part 1:  
Requirements for development,  
validation and routine control of  
a sterilization process for medical  
devices**

**AMENDMENT 2: Revision to 4.3.4 and  
11.2**

*Stérilisation des produits de santé — Irradiation —*

*Partie 1: Exigences relatives à la mise au point, à la validation et au  
contrôle de routine d'un procédé de stérilisation pour les dispositifs  
médicaux*

*AMENDEMENT 2: Révision de 4.3.4 et de 11.2*



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