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AMENDMENT 2
2018-11

**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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