
**Sterilization of health-care products —
Ethylene oxide — Requirements for
the development, validation and
routine control of a sterilization
process for medical devices**

**AMENDMENT 1: Revision of Annex E,
Single batch release**

*Stérilisation des produits de santé — Oxyde d'éthylène — Exigences
de développement, de validation et de contrôle de routine d'un
processus de stérilisation pour des dispositifs médicaux*

AMENDEMENT 1: Révision de l'Annexe E, Libération d'un lot unique





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CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
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