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**Sterilizacija izdelkov za zdravstveno nego - Etilenoksid - Zahteve za razvoj, validacijo in rutinsko kontrolo sterilizacijskih postopkov za medicinske pripomočke (ISO/DIS 11135:2025)**

Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO/DIS 11135:2025)

Sterilisation von Produkten für die Gesundheitsfürsorge - Ethylenoxid - Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (ISO/DIS 11135:2025)

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 (ISO/DIS 11135:2025)

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**Ta slovenski standard je istoveten z: prEN ISO 11135**

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**ICS:**

|           |  |   |
|-----------|--|---|
| 11.080.01 | Sterilizacija in dezinfekcija na splošno | Sterilization and disinfection in general |
|-----------|--|---|

**oSIST prEN ISO 11135:2025**

**en,fr,de**





# DRAFT International Standard

## ISO/DIS 11135

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

*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*

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## ISO/DIS 11135:2025(en)

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This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 204, *Sterilization of medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 11135:2014), which has been technically revised. It also replaces Amendment ISO 11135:2014/Amd 1:2018.

The main changes are as follows:

- addition of guidance in informative [annexes B, D, E, G, H, I](#) and K;
- more defined requirements for microbiological performance qualification (MPQ) in [Annex F](#);
- incorporation of relevant elements of ISO/TS 21387:2020 into [annexes A](#) and [H](#).

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