SLOVENSKI STANDARD
oSIST prEN ISO 11135:2025

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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)

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

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

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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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, J 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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