
Sterilizacija zdravstvenih izdelkov - Biološki indikatorji - 6. del: Biološki indikatorji za sterilizacijske postopke z uparjenim vodikovim peroksidom (ISO/DIS 11138-6:2026)

Sterilization of health care products - Biological indicators - Part 6: Biological indicators for vaporized hydrogen peroxide sterilization processes (ISO/DIS 11138-6:2026)

Sterilisation von Produkten für die Gesundheitsfürsorge - Biologische Indikatoren - Teil 6: Biologische Indikatoren für Sterilisationsverfahren mit Wasserstoffperoxid (ISO/DIS 11138-6:2026)

Stérilisation des produits de santé - Indicateurs biologiques - Partie 6: Indicateurs biologiques pour la stérilisation au peroxyde d'hydrogène (ISO/DIS 11138-6:2026)

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Sterilization of health care products — Biological indicators —

Part 6: Biological indicators for vaporized hydrogen peroxide sterilization processes

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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 102, *Sterilizers and associated equipment for processing of medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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Introduction

ISO 11138-1 specifies production, labelling, test methods and performance requirements for the manufacture of biological indicators including inoculated carriers and suspensions intended for use in validation and monitoring of sterilization processes. This document gives specific requirements for those biological indicators intended for use in vaporized hydrogen peroxide (VH₂O₂) sterilization processes.

The ISO 11138 series represents the current “state-of-the-art” according to the experts representing manufacturers, users and regulatory authorities involved in developing these documents. The intent is not to promote the use of biological indicators where such use is not advised, but rather to provide common requirements for the production of biological indicators that are known to be in use today.

Requirements for the validation and control of VH₂O₂ sterilization are provided in ISO 22441.

NOTE There can be other national or regional standards covering requirements for sterilization or biological indicators.

Guidance on selection, use and interpretation of results when using biological indicators can be found in ISO 11138-7.

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