



SLOVENSKI STANDARD
SIST EN ISO 23500-5:2024

01-julij-2024

**Priprava in vodenje kakovosti tekočin za hemodializo in podobne terapije - 5. del:
Kakovost tekočin za hemodializo in podobne terapije (ISO 23500-5:2024)**

Preparation and quality management of fluids for haemodialysis and related therapies -
Part 5: Quality of dialysis fluid for haemodialysis and related therapies (ISO 23500-
5:2024)

Herstellung und Qualitätsmanagement von Flüssigkeiten für die Hämodialyse und
verwandte Therapien - Teil 5: Qualität von Flüssigkeiten für die Hämodialyse und
verwandte Therapien (ISO 23500-5:2024)

Préparation et management de la qualité des liquides d'hémodialyse et de thérapies
annexes - Partie 5: Qualité des liquides de dialyse pour hémodialyse et thérapies
apparentées (ISO 23500-5:2024)

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11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
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EN ISO 23500-5

NORME EUROPÉENNE

EUROPÄISCHE NORM

April 2024

ICS 11.040.40

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Preparation and quality management of fluids for
haemodialysis and related therapies - Part 5: Quality of
dialysis fluid for haemodialysis and related therapies (ISO
23500-5:2024)

Préparation et management de la qualité des liquides
d'hémodialyse et de thérapies annexes - Partie 5:
Qualité des liquides de dialyse pour hémodialyse et
thérapies apparentées (ISO 23500-5:2024)

Herstellung und Qualitätsmanagement von
Flüssigkeiten für die Hämodialyse und verwandte
Therapien - Teil 5: Qualität von Flüssigkeiten für die
Hämodialyse und verwandte Therapien (ISO 23500-
5:2024)

This European Standard was approved by CEN on 18 April 2024.

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COMITÉ EUROPÉEN DE NORMALISATION
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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 23500-5:2024) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN/TC 205 "Non-active medical devices" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2024, and conflicting national standards shall be withdrawn at the latest by October 2024.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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International Standard

ISO 23500-5

Preparation and quality management of fluids for haemodialysis and related therapies —

Part 5: Quality of dialysis fluid for haemodialysis and related therapies

*Préparation et management de la qualité des liquides
d'hémodialyse et de thérapies annexes —*

*Partie 5: Qualité des liquides de dialyse pour hémodialyse et
thérapies apparentées*

**Second edition
2024-04**

ISO 23500-5:2024(en)

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ISO 23500-5:2024(en)

Foreword

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 23500-5:2019), which has been technically revised.

The main changes are: alternatives to classic microbial analytical methods [endotoxin testing using rFC (tp)] have been incorporated.

A list of all parts of the ISO 23500 series can be found on the ISO website.

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