



**SLOVENSKI STANDARD**  
**SIST EN ISO 23500-4:2024**

**01-julij-2024**

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**Priprava in vodenje kakovosti tekočin za hemodializo in podobne terapije - 4. del:  
Koncentrati za hemodializo in podobne terapije (ISO 23500-4:2024)**

Preparation and quality management of fluids for haemodialysis and related therapies -  
Part 4: Concentrates for haemodialysis and related therapies (ISO 23500-4:2024)

Herstellung und Qualitätsmanagement von Flüssigkeiten für die Hämodialyse und  
verwandte Therapien - Teil 4: Konzentrate für die Hämodialyse und verwandte  
Therapien (ISO 23500-4:2024)

Préparation et management de la qualité des liquides d'hémodialyse et de thérapies  
annexes - Partie 4: Concentrés pour hémodialyse et thérapies apparentées (ISO 23500-  
4:2024)

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**ICS:**

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
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Preparation and quality management of fluids for  
haemodialysis and related therapies - Part 4: Concentrates  
for haemodialysis and related therapies (ISO 23500-  
4:2024)

Préparation et management de la qualité des liquides  
d'hémodialyse et de thérapies annexes - Partie 4:  
Concentrés pour hémodialyse et thérapies apparentées  
(ISO 23500-4:2024)

Herstellung und Qualitätsmanagement von  
Flüssigkeiten für die Hämodialyse und verwandte  
Therapien - Teil 4: Konzentrate für die Hämodialyse  
und verwandte Therapien (ISO 23500-4:2024)

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

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## European foreword

This document (EN ISO 23500-4:2024) 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of an identical text or by endorsement, at the latest by October 2024, and conflicting national standards shall be withdrawn at the latest by October 2024.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 23500-4**

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

### Part 4: Concentrates for haemodialysis and related therapies

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

*Partie 4: Concentrés pour hémodialyse et thérapies apparentées*

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**Second edition  
2024-04**

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### Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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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 23500-4:2019), which has been technically revised.

The main changes are as follows:

- alternatives to classic microbial analytical methods [endotoxin testing using rFC (tp)] have been incorporated;
- further clarifications on the use of concentrates spikes and containers have been added.

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

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