SLOVENSKI STANDARD
SIST EN ISO 23500-4:2024

01-julij-2024

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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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)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents

Page

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of an identical text or by endorsement, at the latest by October 2024, and conflicting national standards shall be withdrawn at the latest by October 2024.

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Endorsement notice

The text of ISO 23500-4:2024 has been approved by CEN as EN ISO 23500-4:2024 without any modification.

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

Second edition
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Contents

Page

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 23500-4:2019), 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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