



International Standard

Redline version
compares Second edition
to First edition



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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This Redline version provides you with a quick and easy way to compare all the changes between this standard and its previous edition. A vertical bar appears in the margin wherever a change has been made. Additions and deletions are displayed in red, with deletions being struck through.



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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 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 ~~first~~ **second** edition cancels and replaces ~~the first edition (ISO 13958:2014)~~ **the first edition (ISO 13958:2014)**, which has been technically revised. ~~The main changes compared to the previous edition are as follows.~~

The main changes are as follows:

- ~~The document forms part of a revised and renumbered series dealing with the preparation and quality management of fluids for haemodialysis and related therapies. The series comprise ISO 23500-1 (previously ISO 23500), ISO 23500-2, (previously ISO 26722), ISO 23500-3, (previously ISO 13959), ISO 23500-4, (previously ISO 13958), and ISO 23500-5, (previously ISO 11663).~~
- 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.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.