



SLOVENSKI STANDARD

SIST EN ISO 23500-3:2019

01-maj-2019

Nadomešča:
SIST EN ISO 13959:2016

**Priprava in vodenje kakovosti tekočin za hemodializo in podobne terapije - 3. del:
Voda za hemodializo in podobne terapije (ISO 23500-3:2019)**

Preparation and quality management of fluids for haemodialysis and related therapies -
Part 3: Water for haemodialysis and related therapies (ISO 23500-3:2019)

Leitfaden für die Vorbereitung und das Qualitätsmanagement von Konzentraten für die
Hämodialyse und verwandte Therapien - Teil 3: Wasser für die Hämodialyse und
verwandte Therapien (ISO 23500-3:2019)

Préparation et management de la qualité des liquides d'hémodialyse et de thérapies
annexes - Partie 3: Eau pour hémodialyse et thérapies apparentées (ISO 23500-3:2019)

Ta slovenski standard je istoveten z: EN ISO 23500-3:2019

ICS:

11.120.99	Drugi standardi v zvezi s farmacijo	Other standards related to pharmaceutics
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EUROPEAN STANDARD

EN ISO 23500-3

NORME EUROPÉENNE

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Preparation and quality management of fluids for haemodialysis and related therapies - Part 3: Water for haemodialysis and related therapies (ISO 23500-3:2019)

Préparation et management de la qualité des liquides
d'hémodialyse et de thérapies annexes - Partie 3: Eau
pour hémodialyse et thérapies apparentées (ISO
23500-3:2019)

Leitfaden für die Vorbereitung und das
Qualitätsmanagement von Konzentraten für die
Hämodialyse und verwandte Therapien - Teil 3:
Wasser für die Hämodialyse und verwandte Therapien
(ISO 23500-3:2019)

This European Standard was approved by CEN on 14 January 2019.

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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 23500-3:2019) 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of an identical text or by endorsement, at the latest by September 2019, and conflicting national standards shall be withdrawn at the latest by September 2019.

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.

This document supersedes EN ISO 13959:2015.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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The text of ISO 23500-3:2019 has been approved by CEN as EN ISO 23500-3:2019 without any modification.

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INTERNATIONAL
STANDARD

ISO
23500-3

First edition
2019-02

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

**Part 3:
Water for haemodialysis and related
therapies**

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

Partie 3: Eau pour hémodialyse et thérapies apparentées

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This first edition cancels and replaces ISO 13959:2014, which has been technically revised. The main changes compared to the previous edition 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).

A list of all parts in 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.

Introduction

Assurance of adequate water quality is one of the most important aspects of ensuring a safe and effective delivery of haemodialysis, haemodiafiltration, or haemofiltration.

This document contains minimum requirements, chemical and microbiological, for the water to be used for preparation of dialysis fluids, concentrates, and for the reprocessing of haemodialysers and the necessary steps to ensure conformity with those requirements.

Haemodialysis and related therapies such as haemodiafiltration can expose the patient to more than 500 l of water per week across the semi-permeable membrane of the haemodialyser or haemodiafilter. Healthy individuals seldom have a weekly oral intake above 12 l. This over 40-fold increase in exposure requires control and regular surveillance of water quality to avoid excesses of known or suspected harmful substances. Since knowledge of potential injury from trace elements and contaminants of microbiological origin over long periods is still growing and techniques for treating drinking water are continuously developed, this document will evolve and be refined accordingly. The physiological effects attributable to the presence of organic contaminants in dialysis water are important areas for research, however, the effect of such contaminants on patients receiving regular dialysis treatment is largely unknown, consequently no threshold values for organic contaminants permitted in water used for the preparation of dialysis fluids, concentrates, and reprocessing of haemodialysers has been specified in this revised document.

Within this document, measurement techniques current at the time of publication have been cited. Other standard methods can be used, provided that such methods have been appropriately validated and are comparable to the cited methods.

The final dialysis fluid is produced from concentrates or salts manufactured, packaged, and labelled according to ISO 23500-4 mixed with water meeting the requirements of this document. Operation of water treatment equipment and haemodialysis systems, including on-going surveillance of the quality of water used to prepare dialysis fluids, and handling of concentrates and salts are the responsibility of the haemodialysis facility and are addressed in ISO 23500-1. Haemodialysis professionals make choices about the various applications (haemodialysis, haemodiafiltration, haemofiltration) and should understand the risks of each and the requirements for safety for fluids used for each.

This document is directed towards manufacturers and providers of water treatment systems and also to haemodialysis facilities.

The rationale for the development of this document is given in informative [Annex A](#).

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