SLOVENSKI STANDARD
SIST EN ISO 23500-4:2019

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Nadomešča:
SIST EN ISO 13958:2016

Priprava in vodenje kakovosti tekočin za hemodializo in podobne terapije - 4. del: Koncentrati za hemodializo in podobne terapije (ISO 23500-4:2019)

Preparation and quality management of fluids for haemodialysis and related therapies - Part 4: Concentrates for haemodialysis and related therapies (ISO 23500-4:2019)

Leitfaden für die Vorbereitung und das Qualitätsmanagement von Konzentraten für die Hämodialyse und verwandte Therapien - Teil 4: Konzentrate für die Hämodialyse und verwandte Therapien (ISO 23500-4:2019)

Préparation et management de la qualité des liquides d'hémodialyse et de thérapies annexes - Partie 4: Concentrés pour hémodialyse et thérapies apparentées (ISO 23500-4:2019)

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Preparation and quality management of fluids for haemodialysis and related therapies - Part 4: Concentrates for haemodialysis and related therapies (ISO 23500-4:2019)

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Leitfaden für die Vorbereitung und das Qualitätsmanagement von Konzentraten für die Hämodialyse und verwandte Therapien - Teil 4: Konzentrate für die Hämodialyse und verwandte Therapien (ISO 23500-4:2019)

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European foreword

This document (EN ISO 23500-4:2019) 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of an identical text or by endorsement, at the latest by September 2019, and conflicting national standards shall be withdrawn at the latest by September 2019.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.

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Endorsement notice

The text of ISO 23500-4:2019 has been approved by CEN as EN ISO 23500-4:2019 without any modification.

INTERNATIONAL STANDARD

ISO 23500-4

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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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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).

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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 13958:2014, 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 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.

Introduction

The requirements and goals established by this document will help ensure the effective, safe performance of haemodialysis concentrates and related materials. This document reflects the conscientious efforts of concerned physicians, clinical engineers, nurses, dialysis technicians and dialysis patients, in consultation with device manufacturers and regulatory agency representatives, to develop a standard for performance levels that could be reasonably achieved at the time of publication. The term “consensus” as applied to the development of voluntary medical device standards does not imply unanimity of opinion, but rather reflects the compromise necessary in some instances when a variety of interests shall be merged.

The rationale for the development of this document is given in informative Annex A.

Throughout this document, requirements and recommendations are made to use ISO-quality water. Therefore, it is recommended to refer to ISO 23500-3 along with this document.

For the purpose of this document, “concentrates” are a mixture of chemicals and water, or chemicals in the form of dry powder or other highly concentrated media, which are delivered to the end user to make dialysis fluid used to perform haemodialysis and related therapies.

