SLOVENSKI STANDARD
SIST EN ISO 23500-5:2019

01-maj-2019

Nadomešča:
SIST EN ISO 11663:2016

Priprava in vodenje kakovosti tekočin za hemodializo in podobne terapije - 5. del: Kakovost tekočin za hemodializo in podobne terapije (ISO 23500-5:2019)

Preparation and quality management of fluids for haemodialysis and related therapies - Part 5: Quality of dialysis fluid for haemodialysis and related therapies (ISO 23500-5:2019)

Vorbereitung und Qualitätsmanagement von Konzentraten für die Hämodialyse und verwandte Therapien - Teil 5: Qualität von Flüssigkeiten für die Hämodialyse und verwandte Therapien (ISO 23500-5:2019)

Préparation et management de la qualité des liquides d'hémodialyse et de thérapies annexes - Partie 5: Qualité des liquides de dialyse pour hémodialyse et thérapies apparentées (ISO 23500-5:2019)

Ta slovenski standard je istoveten z: **EN ISO 23500-5:2019**

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

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EUROPEAN STANDARD

NORME EUROPÉENNE

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Preparation and quality management of fluids for haemodialysis and related therapies - Part 5: Quality of dialysis fluid for haemodialysis and related therapies (ISO 23500-5:2019)

Préparation et management de la qualité des liquides d'hémodialyse et de thérapies annexes - Partie 5: Qualité des liquides de dialyse pour hémodialyse et thérapies apparentées (ISO 23500-5:2019)

Vorbereitung und Qualitätsmanagement von Konzentraten für die Hämodialyse und verwandte Therapien - Teil 5: Qualität von Flüssigkeiten für die Hämodialyse und verwandte Therapien (ISO 23500-5:2019)

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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

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European foreword

This document (EN ISO 23500-5:2019) 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of an identical text or by endorsement, at the latest by September 2019, and conflicting national standards shall be withdrawn at the latest by September 2019.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 11663:2015.

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Endorsement notice

The text of ISO 23500-5:2019 has been approved by CEN as EN ISO 23500-5:2019 without any modification.

INTERNATIONAL STANDARD

ISO 23500-5

First edition
2019-02

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

Part 5: Quality of dialysis fluid for haemodialysis and related therapies

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

Partie 5: Qualité des liquides de dialyse pour hémodialyse et thérapies apparentées

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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 11663:2014, 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

Haemodialysis patients are directly exposed to large volumes of dialysis fluid, with the dialyser membrane being the only barrier against transfer of hazardous contaminants from the dialysis fluid to the patient. It has long been known that there could be hazardous contaminants in the water and concentrates used to prepare the dialysis fluid. To minimize this hazard, ISO 23500-3 and ISO 23500-4 set forth quality requirements for the water and concentrates used to prepare dialysis fluid. However, if the dialysis fluid is not prepared carefully, it could contain unacceptable levels of contaminants even though it is prepared from water and concentrates, conforming to the requirements of ISO 23500-3 and ISO 23500-4. Further, the dialysis fluid might be used as the starting material for the online preparation of fluids intended for infusion into the patient, for example, in therapies such as online haemodiafiltration. For these reasons, this document for dialysis fluid quality was developed to complement the existing International Standards for water and concentrates, ISO 23500-3 and ISO 23500-4, respectively. Guidelines to aid the user in routinely meeting the requirements of this document and ISO 23500-3 can be found in ISO 23500-1.

Within these International Standards, measurement techniques current at the time of preparation 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 rationale for the development of this document is given in Annex A.

This document reflects the conscientious efforts of healthcare professionals, patients, and medical device manufacturers to develop recommendations for the quality of dialysis fluid. This document is directed at the healthcare professionals involved in the management of dialysis facilities and the routine care of patients treated in dialysis facilities, since they are responsible for the final preparation of dialysis fluid. The recommendations contained in this document are not intended for regulatory application.

This document aims to help protect haemodialysis patients from adverse effects arising from known chemical and microbiological contaminants that can be found in improperly prepared dialysis fluid. However, the physician in charge of dialysis has the ultimate responsibility for ensuring that the dialysis fluid is correctly formulated and meets the applicable quality standards.

The concepts incorporated in this document should not be considered inflexible or static. The requirements and recommendations presented here should be reviewed periodically in order to assimilate increased understanding of the role of dialysis fluid purity in patient outcomes and technological developments.