



Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN 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

Préparation et management de la qualité
des liquides d'hémodialyse et de
thérapies annexes - Partie 5: Qualité des
liquides de dialyse pour hémodialyse et

Herstellung und Qualitätsmanagement
von Konzentraten für die Hämodialyse
und verwandte Therapien - Teil 5:
Qualität von Flüssigkeiten für die

National Foreword

This European Standard EN ISO 23500-5:2019 was adopted as Luxembourgish Standard ILNAS-EN ISO 23500-5:2019.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

<https://portail-qualite.public.lu/fr/normes-normalisation/participer-normalisation.html>

THIS PUBLICATION IS COPYRIGHT PROTECTED

Nothing from this publication may be reproduced or utilized in any form or by any mean - electronic, mechanical, photocopying or any other data carries without prior permission!

English Version

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)

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

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.



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..... | 3 |

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.

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.

Endorsement notice

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

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*



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2019

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Published in Switzerland

Contents

| | Page |
|--|-----------|
| Foreword | iv |
| Introduction | v |
| 1 Scope | 1 |
| 2 Normative references | 1 |
| 3 Terms and definitions | 1 |
| 4 Requirements | 2 |
| 4.1 Microbiological contaminants in dialysis fluid | 2 |
| 4.1.1 General | 2 |
| 4.1.2 Microbiological requirements for standard dialysis fluid | 2 |
| 4.1.3 Microbiological requirements for ultrapure dialysis fluid | 2 |
| 4.1.4 Microbiological requirements for online prepared substitution fluid | 2 |
| 4.2 Chemical contaminants in dialysis fluid | 3 |
| 5 Tests for conformity with microbiological requirements | 3 |
| 5.1 Sampling | 3 |
| 5.2 Culture methods | 3 |
| Annex A (informative) Rationale for the development and provisions of this document | 5 |
| Annex B (informative) Reference tables | 8 |
| Bibliography | 11 |