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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 43050-2023

**Preparation and quality management of fluids for
haemodialysis and related therapies - General requirements**

血液透析和相关治疗用液体的制备和质量管理 通用要求

(English Translation)

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Reference

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents" Drafting.

This document has been modified to adopt ISO 23500-1:2019 "Preparation and quality management of hemodialysis and related treatment liquids - Part 1: General requirements" beg". Compared with ISO 23500-1:2019, the main technical differences between this document and ISO 23500-1:2019 are as follows.

---Added YY/T 0793.1-2022;

---Replaced ISO 23500-5 with normatively quoted YY/T 0793.4-2022 to adapt to my country's national conditions;

---Changed the expressions related to the disinfection process in 8.3.2.2 to adapt to domestic clinical practice;

---Deleted the content related to online preparation of replacement fluid and dialyzer reuse in ISO 23500-1:2019 to comply with relevant regulations in my country regulations;

---8.3.3.2.1, 8.3.3.3, 8.3.4, and relevant content from the "Pharmacopoeia of the People's

Republic of China" have been added to A.10 in Appendix A to improve the applicability of the method in the country.

The following editorial changes have been made to this document.

---Change the name of the standard to "General Requirements for the Preparation and Quality Management of Hemodialysis and Related Therapeutic Fluids";

---Added 3.4 middle note and changed B.4.5 middle note;

---Deleted Note 2 in ISO 23500-1:2019 Terms and Definitions 3.30;

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Introduction

This document is the basic standard for a series of standards for water treatment and dialysate production, providing users with information on water treatment, concentrate treatment and hemodialysis.

Guidance on the production and quality supervision of dialysate for use. The quality of dialysis fluids is the responsibility of dialysis professionals and is an important factor in daily hemodialysis safety.

It is the key to be fully effective, so it is necessary to provide relevant requirements.

Appendix A further explains the basis for the formation and provision of technical terms.

Under normal circumstances, the equipment used in the dialysate preparation stage is provided by professional suppliers, and the maintenance of the equipment after installation is performed by dialysis professionals.

members are responsible. This document provides quality monitoring and maintenance guidelines for equipment to ensure that dialysate quality remains stable and within an acceptable range. suggestion the user operates and maintains the equipment according to the instructions of the professional manufacturer. If there is no professional manufacturer, the user is responsible for ensuring that the equipment is used in the hemodialysis facility.

performance during installation, and appropriate operation and maintenance manuals should be available.

Appendix B provides further description of water treatment systems, concentrate preparation, and dialysate preparation in dialysis facilities for users to understand certain

It provides basic knowledge on the usage principles and configuration methods of some specific equipment rather than providing detailed design standards. Water treatment equipment is suitable for YY/T 0793.1-2022.