International

ISO 23500-4

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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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 23500-4:2019), which has been technically revised.

The main changes are as follows:

— alternatives to classic microbial analytical methods [endotoxin testing using rFC (tp)] have been incorporated;

— further clarifications on the use of concentrates spikes and containers have been added.

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.

The requirements established in this document will help ensure the effective, safe performance of haemodialysis concentrates and related materials. Haemodialysis 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. In this document, the dialysis fluid made by the end user mixing haemodialysis concentrate and water of the quality given in ISO 23500-3 is discussed to help clarify the requirements for manufacturing concentrates. Therefore, it is recommended to refer to ISO 23500-3 along with this document.

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. 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 are merged.

Because the manufacturer of the concentrate does not have control over the final dialysis fluid, any reference to dialysis fluid is for clarification and is not a requirement of the manufacturer, Furthermore, label requirements for dialysis fluid are placed on the labelling of the concentrate, it is the user's responsibility to ensure proper use.

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