

Concentrates for haemodialysis and related therapies

ICS 11.120.99

National foreword

This British Standard is the UK implementation of EN 13867:2002+A1:2009. It supersedes BS EN 13867:2002 which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to CEN text carry the number of the CEN amendment. For example, text altered by CEN amendment A1 is indicated by **A1** **A1**.

The UK participation in its preparation was entrusted by Technical Committee CH/150, Implants for surgery, to Subcommittee CH/150/2, Cardiovascular implants.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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English Version

Concentrates for haemodialysis and related therapies

Concentrés pour hémodialyse et thérapies associées

Konzentrate für die Hämodialyse und verwandte Therapien

This European Standard was approved by CEN on 30 December 2001 and includes Amendment 1 approved by CEN on 16 May 2009.

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Foreword

This document (EN 13867:2002+A1:2009) has been prepared by 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of an identical text or by endorsement, at the latest by December 2009 and conflicting national standards shall be withdrawn at the latest by March 2010.

This document includes Amendment 1, approved by CEN on 2009-05-16.

This document supersedes EN 13867:2002.

The start and finish of text introduced or altered by amendment is indicated in the text by tags **A1** **A1**.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

For A-deviations, see Annex ZB.

Annexes A, ZA and ZB are for information only.

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Introduction

Dialysing fluids contain electrolytes in concentrations approaching that of the composition of normal extra-cellular body fluid. They can also contain non-electrolytes such as dextrose. Dialysing fluid quality plays a key role in the safety and biocompatibility of the dialysis treatment. Because of the large volumes employed, dialysing fluids are generally prepared by diluting concentrates with water of suitable quality.

The manufacturer of concentrates should utilize raw materials and techniques to minimize microbial contamination (a low bioburden). The concentrates should be stored in conditions that assure the maintenance of this low level.

During the dilution and use of these concentrates it is essential to take precautions to minimize any microbial contamination.

The dialysing fluid is prepared from concentrates manufactured, packaged and labelled according to this standard, mixed with defined large proportions of water meeting national requirements on water for dialysis. Operation of water treatment equipment, selection and handling of concentrates after delivery to the hospital or clinic, and operation of the dialysis equipment are the responsibility of the dialysis facility.

The properties of the final mixed dialysing fluids are not within the control of concentrate manufacturers. This standard does not address the important clinical and technical processes connected with the selection of concentrates and preparation of dialysing fluids. Dialysis professionals make choices about the various applications (e.g. haemodialysis, haemodiafiltration, haemofiltration) and it is essential they understand the corresponding risks and the requirements for safety of fluids used for each therapy.