Vere dialüüsi ja sellega seotud ravi kontsentraadid KONSOLIDEERITUD TEKST

Concentrates for haemodialysis and related therapies
CONSOLIDATED TEXT

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Standard on kinnitatud Eesti Standardikeskuse 30.11.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.11.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
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ICS 11.040.20, 11.120.99

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 13867:2002+A1

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ICS 11.040.20; 11.120.99

Supersedes EN 13867:2002

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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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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of an identical text or by endorsement, at the latest by December 2009 and conflicting national standards shall be withdrawn at the latest by March 2010.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.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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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.

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1 Scope

This European Standard specifies requirements for dry and liquid concentrates to be diluted for use as dialysing fluids in haemodialysis or related therapies. It addresses chemical and microbiological quality and purity, handling and labelling of concentrates, the requirements for containers and the tests to monitor chemical and microbiological contents and quality of such concentrates.

This European standard does not address the final mixing and use of these concentrates or the treated water used in connection with haemodialysis and related therapies.

This European standard does not apply to dialysing fluid regeneration systems.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 556, *Sterilization of medical devices – Requirements for medical devices to be labelled "Sterile"*

EN 980, *Graphical symbols for use in the labelling of medical devices*

EN 1174-1, *Sterilization of medical devices – Estimation of the population of micro-organisms on product – Part 1: Requirements*

EN 1174-2, *Sterilization of medical devices - Estimation of the population of micro-organisms on product – Part 2: Guidance*

EN 1174-3, *Sterilization of medical devices – Estimation of the population of micro-organisms on product – Part 3: Guide to the methods for validation of microbiological techniques*

European Pharmacopoeia 3rd edition: 1999 (including supplements 2000 and 2001)

3 Terms and definitions

For the purpose of this European standard, the following terms and definitions apply:

3.1
acetate dialysing fluid
dialysing fluid without bicarbonate, using acetate as a buffer

NOTE Acetate dialysing fluid is generally produced from a single concentrate.

3.2
batch system
system in which water and concentrate(s) are mixed in one tank and the resulting fluid used for haemodialysis or related therapies

3.3
bicarbonate dialysing fluid
dialysing fluid containing physiological or higher concentrations of bicarbonate as buffer

NOTE Bicarbonate dialysing fluid is produced by mixing two or more concentrates.

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