SLOVENSKI STANDARD
SIST EN 13867:2003/kprA1:2009

01-april-2009

Koncentrati za hemodializo in podobne terapije

Concentrates for haemodialysis and related therapies

Konzentrate für die Hämodialyse und verwandte Therapien

Concentrés pour hémodialyse et thérapies associées

Ta slovenski standard je istoveten z: EN 13867:2002/prA1

ICS:

11.120.99	Drugi standardi v zvezi s farmacijo	Other standards related to pharmaceutics

SIST EN 13867:2003/kprA1:2009 en,fr

EUROPEAN STANDARD

NORME EUROPÉENNE

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FINAL DRAFT
EN 13867:2002

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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 draft amendment is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 205.

This draft amendment A1, if approved, will modify the European Standard EN 13867:2002. If this draft becomes an amendment, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration.

This draft amendment was established by CEN 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 Management Centre has the same status as the official versions.

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

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1 Modification to Annex ZA 4

Foreword

This document (EN 13867:2002/prA1:2009) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

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.

1 Modification to Annex ZA

Replace the existing Annex ZA with the following:

"

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC "Medical Devices"

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC "Medical Devices".

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC "Medical Devices"

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	1, 2, 3, 4, 5, 6, 7.1	
4.2	8.1	
4.5	8.1, 8.3, 8.4, 8.5	
4.6	7.2, 7.3, 7.5, 7.6, 8.3, 8.4, 8.6	
4.7	7.2, 8.1, 8.3, 8.4, 8.5	
5	3, 4, 5, 13.1	
5.2	7.3, 13.3a), b), j), 13.4	Partly addressed
5.2e)	9.1, 9.2, 13.3k)	
5.2f)	13.3i), k)	
5.2h)	9.1, 13.3i), j)	
5.2i)	9.1, 13.3i), j)	
5.2j)	13.3b)	
5.2k)	8.7, 13.3c), m)	
5.2l)	13.3e)	
5.2m)	13.3d)	
5.2n)	13.3k)	
5.2o)	13.3i), k)	

5.3	13.3a), b), 13.4	Partly addressed
5.3e)	13.3i), j), k)	
5.4	13.4, 13.6a), b)	
5.4c)	13.6c)	
5.4e)	13.6f), m)	
5.5	13.2	
	13.3q)	This relevant Essential Requirement is not addressed in this European Standard

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard."