



SLOVENSKI STANDARD SIST EN ISO 8536-1:2003

01-september-2003

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SIST EN ISO 8536-1:2000

SIST EN ISO 8536-1:2000/AC:2000

Infuzijska oprema za uporabo v medicini - 1. del: Infuzijske steklenice (ISO 8536-1:2000)

Infusion equipment for medical use - Part 1: Infusion glass bottles (ISO 8536-1:2000)

Infusionsgeräte zur medizinischen Verwendung - Teil 1: Infusionsflaschen aus Glas (ISO 8536-1:2000)

Matériel de perfusion a usage médical - Partie 1: Flacons en verre pour perfusion (ISO 8536-1:2000)

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Ta slovenski standard je istoveten z: EN ISO 8536-1:2003

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment
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en

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English version

Infusion equipment for medical use - Part 1: Infusion glass
bottles (ISO 8536-1:2000)

Matériel de perfusion à usage médical - Partie 1: Flacons
en verre pour perfusion (ISO 8536-1:2000)

Infusionsgeräte zur medizinischen Verwendung - Teil 1:
Infusionsflaschen aus Glas (ISO 8536-1:2000)

This European Standard was approved by CEN on 27 December 2002.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists 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 Management Centre has the same status as the official versions.

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CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and United Kingdom.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Foreword

The text of ISO 8536-1:2000 has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical and pharmaceutical use" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 8536-1:2003 by CMC.

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 November 2003, and conflicting national standards shall be withdrawn at the latest by November 2003.

This document supersedes EN ISO 8536-1:1999.

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

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

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Endorsement notice

The text of ISO 8536-1:2000 has been approved by CEN as EN ISO 8536-1:2003 without any modifications.

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Annex ZA (informative)

A-deviations

A-deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of CEN/CENELEC member:

NOTE: Where standards fall under EC Directives it is the view of the Commission of the European Communities (OJ No G 59, 9.3, 1982) that the effect of the decision of the Court of Justice in case 815/79 Cremonini/Vrankovitch (European Court Reports 1980, p.3583) is that compliance with A-deviations is no longer mandatory and that the free movement of products complying with such a standard should not be restricted except under the safeguard procedure provided for in the relevant Directive.

A-deviations in an EFTA country are valid instead of the relevant provisions of the European Standard in that country until they have been removed.

The European Standard is not in agreement with the European Pharmacopoeia 2nd edition VI.2.3.1, which is mandatory in Sweden, by LVFS 1996:16.

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**Infusion equipment for medical use —
Part 1:
Infusion glass bottles**

Matériel de perfusion à usage médical —

Partie 1: Flacons en verre pour perfusion

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