SLOVENSKI STANDARD
SIST EN ISO 8362-4:2005

01-januar-2005

Nadomeģ a:
SIST EN 28362-4:2000

Vsebniki za parenteralne farmacevtske oblike in dodatna oprema - 4. del: Viale iz litega stekla (ISO 8362-4:2003)

Injection containers and accessories - Part 4: Injection vials made of moulded glass (ISO 8362-4:2003)

Injektionsbehältnisse und Zubehör - Teil 4: Injektionsflaschen aus Hüttenglas (ISO 8362-4:2003)

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Récipients et accessoires pour produits injectables - Partie 4: Flacons en verre moulé (ISO 8362-4:2003)

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Ta slovenski standard je istoveten z: **EN ISO 8362-4:2004**

ICS:

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

SIST EN ISO 8362-4:2005 **en,fr,de**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8362-4

June 2004

ICS 11.040.20

Supersedes EN 28362-4:1993

English version

Injection containers and accessories - Part 4: Injection vials made of moulded glass (ISO 8362-4:2003)

Récipients et accessoires pour produits injectables - Partie 4: Flacons en verre moulé (ISO 8362-4:2003)

Injektionsbehältnisse und Zubehör - Teil 4: Injektionsflaschen aus Hüttenglas (ISO 8362-4:2003)

This European Standard was approved by CEN on 1 April 2004.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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

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

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Foreword

The text of ISO 8362-4:2003 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 8362-4:2004 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 December 2004, and conflicting national standards shall be withdrawn at the latest by December 2004.

This document supersedes EN 28362-4:1993.

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

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Endorsement notice

The text of ISO 8362-4:2003 has been approved by CEN as EN ISO 8362-4:2004 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, 4th Edition, § 3.2.1 "Glass containers for pharmaceutical use", which is mandatory in Sweden by "Svensk Läkemedelsstandard 2004:1, page 25" and "Regulation LVFS 2004:1.

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INTERNATIONAL STANDARD

ISO 8362-4

Second edition
2003-08-01

Injection containers and accessories —

Part 4: Injection vials made of moulded glass

Récipients et accessoires pour produits injectables —

Partie 4: Flacons en verre moulé

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