SLOVENSKI STANDARD
SIST EN ISO 9187-1:2003

01-september-2003

Nadomeġļa:
SIST EN ISO 9187-1:2000
SIST EN ISO 9187-1:2000/AC:2000

Oprema za injiciranje za uporabo v medicini - 1. del: Ampule za paranteralne farmacevtske oblike (ISO 9187-1:2000)

Injection equipment for medical use - Part 1: Ampoules for injectables (ISO 9187-1:2000)

Infusionsgeräte zur medizinischen Verwendung - Teil 1: Ampullen für Injektionspräparate (ISO 9187-1:2000)

Matériel d'injection a usage médical - Partie 1: Ampoules pour produits injectables (ISO 9187-1:2000)

Ta slovenski standard je istoveten z: **EN ISO 9187-1:2003**

ICS:

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

SIST EN ISO 9187-1:2003 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 9187-1

May 2003

ICS 11.040.20

Supersedes EN ISO 9187-1:1999

English version

Injection equipment for medical use - Part 1: Ampoules for injectables (ISO 9187-1:2000)

Matériel d'injection à usage médical - Partie 1: Ampoules pour produits injectables (ISO 9187-1:2000)

Infusionsgeräte zur medizinischen Verwendung - Teil 1: Ampullen für Injektionspräparate (ISO 9187-1:2000)

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.

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.

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

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

Ref. No. EN ISO 9187-1:2003 E

Foreword

The text of ISO 9187-1:2000 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 9187-1:2003 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 9187-1:1999.

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.

Endorsement notice

The text of ISO 9187-1:2000 has been approved by CEN as EN ISO 9187-1:2003 without any modifications.

NOTE Normative references to International Standards are listed in annex ZB (normative).

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.

Annex ZB
(normative)

Normative references to international publications with their relevant European publications

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).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

Publication	Year	Title	EN	Year
ISO 7500-1	1999	Metallic materials - Verification of static uniaxial testing machines - Part 1: Tension/compression testing machines	EN ISO 7500-1	1999

INTERNATIONAL STANDARD

ISO 9187-1

Second edition
2000-05-01

Injection equipment for medical use —

Part 1: Ampoules for injectables

Matériel d'injection à usage médical —

Partie 1: Ampoules pour produits injectables

Reference number
ISO 9187-1:2000(E)

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Printed in Switzerland

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