SLOVENSKI STANDARD
SIST EN ISO 9187-1:2000

01-januar-2000

Oprema za injiciranje za uporabo v medicini - 1. del: Ampule za paranteralne farmacevtske oblike (ISO 9187-1:1999)

Injection equipment for medical use - Part 1: Ampoules for injectables (ISO 9187-1:1999)

Injektionsgeräte zur medizinischen Verwendung - Teil 1: Ampullen für Injektionspräparate (ISO 9187-1:1999)

Matériel d'injection a usage médical - Partie 1: Ampoules pour produits injectables (ISO 9187-1:1999)

Ta slovenski standard je istoveten z: **EN ISO 9187-1:1999**

ICS:

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

SIST EN ISO 9187-1:2000 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 9187-1

February 1999

ICS 11.040.00

English version

Injection equipment for medical use - Part 1: Ampoules for injectables (ISO 9187-1:1999)

Matériel d'injection à usage médical - Partie 1: Ampoules pour produits injectables (ISO 9187-1:1999)

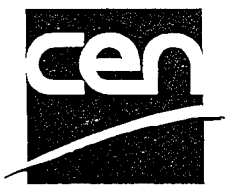
Injektionsgeräte zur medizinischen Verwendung - Teil 1: Ampullen für Injektionspräparate (ISO 9187-1:1999)

This European Standard was approved by CEN on 9 January 1999.

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.

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



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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Foreword

The text of the International Standard from Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical use" of the International Organization for Standardization (ISO) has been taken over as an European Standard by Technical Committee CEN/TC "Non-active medical devices", the secretariat of which is held by BSI.

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 August 1999, and conflicting national standards shall be withdrawn at the latest by August 1999.

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, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 9187-1:1999 has been approved by CEN as a European Standard without any modification.

INTERNATIONAL STANDARD

ISO 9187-1

First edition
1991-06-15

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 : 1991 (E)

Contents

International Organization for Standardization
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 9187 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use.*

ISO 9187 will consist of the following parts under the general title *Injection equipment for medical use*:

— *Part 1: Ampoules for injectables*

— *Part 2: OPC-ampoules*

Introduction

Ampoules are suitable primary packaging materials for storing pharmaceutical products until they are administered to the patient. Owing to the direct contact between injectables and the primary container over extended storage periods, possible interactions must be avoided in order to guarantee patient safety. Adequate means to achieve this objective include proper selection of primary packaging materials, the choice of suitable package design and the availability of specific requirements and methods for testing individual container systems.

Four standardized forms of ampoules (forms A, B, C and D) have, in the past, been in widespread use; however, form A is no longer necessary for the pharmaceutical industry and, consequently, has not been included in this International Standard. To avoid any likelihood of confusion between manufacturers and users, it was decided to retain the same designation letters (i.e. B, C and D) for the forms of ampoule in current use and to disregard the letter A.

It is known that different dimensions of ampoules exist at present in various countries as standard versions. Many countries have already switched over to the dimensions laid down in this part of ISO 9187. All other countries whose ampoules do not yet comply with the dimensions laid down in this part of ISO 9187 should switch over within a period of three years after publication.

Injection equipment for medical use — Ampoules for injectables

1 Scope

This part of ISO 9187 specifies materials, dimensions and capacities, and performance and packaging requirements for three forms of glass ampoules (forms B, C and D) for injectables.

It applies to ampoules with and without a colour break ring.

If ampoules with colour break ring are requested by the user, this should be agreed between manufacturer and user, including a decision on break ring colour.

Ampoules complying with this part of ISO 9187 are intended for single use only.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 9187. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 9187 are encouraged to investigate the possibility of applying the most recent editions of the standards listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 720 : 1985, *Glass — Hydrolytic resistance of glass grains at 121 °C — Method of test and classification.*

ISO 2859-1 : 1989, *Sampling procedures for inspection by attributes — Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection.*

ISO 4802-1 : 1988, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 1: Determination by titration method and classification.*

ISO 7500-1 : 1986, *Metallic materials — Verification of static uniaxial testing machines — Part 1: Tensile testing machines.*