



SLOVENSKI STANDARD
SIST EN ISO 9187-2:2000
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Injection equipment for medical use - Part 2: One-point-cut (OPC) ampoules (ISO 9187-2:1999)

Injektionsgeräte zur medizinischen Verwendung - Teil 2: OPC-Ampullen (ISO 9187-2:1999)

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Matériel d'injection a usage médical - Partie 2: Ampoules a un seul point de cassure (OPC) (ISO 9187-2:1999)

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ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment
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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 9187-2

February 1999

ICS 11.040.20

English version

Injection equipment for medical use - Part 2: One-point-cut
(OPC) ampoules (ISO 9187-2:1999)

Matériel d'injection à usage médical - Partie 2: Ampoules à
un seul point de cassure (OPC) (ISO 9187-2:1999)

Injektionsgeräte zur medizinischen Verwendung - Teil 2:
OPC-Ampullen (ISO 9187-2:1999)

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.

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

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

Page 2
EN ISO 9187-2:1999

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 9187-2:1999 has been approved by CEN as a European Standard without any modification.

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INTERNATIONAL STANDARD

ISO 9187-2

First edition
1993-06-15

Injection equipment for medical use —

Part 2:

One-point-cut (OPC) ampoules

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Matériel d'injection à usage médical —

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Reference number
ISO 9187-2:1993(E)

Contents

	Page
1 Scope	1
2 Normative reference	1
3 Dimensions and designation	1
4 Material	1
5 Requirements	2
6 Delivery	3
7 Packaging	3
8 Marking	3

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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 9187-2 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use*.

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

- Part 1: *Ampoules for injectables*
- Part 2: *One-point-cut (OPC) ampoules*

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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.

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Injection equipment for medical use —

Part 2: One-point-cut (OPC) ampoules

1 Scope

This part of ISO 9187 specifies materials, dimensions and requirements for forms of one-point-cut (OPC) ampoules (forms B, C and D) for injectables.

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

(cl) complying with the requirements of this part of ISO 9187:

Ampoule ISO 9187-2 - OPC - B - 10 - cl

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 9187. At the time of publication, the edition indicated was 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 edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 9187-1:1991, *Injection equipment for medical use — Part 1: Ampoules for injectables*.

3 Dimensions and designation

3.1 Dimensions

The dimensions for OPC ampoules shall be as laid down in ISO 9187-1 and as given in table 1. See figure 1 for typical examples.

3.2 Designation

Designation example of a form B OPC ampoule with a nominal volume of 10 ml, made of colourless glass

4 Material

The material shall be in accordance with ISO 9187-1:1991, clause 4.

Table 1 — Dimensions of OPC ampoules

Dimensions in millimetres

Nom- inal vol- ume	Diameter of point	Distance from bottom line to upper line of point	Wall thickness at constriction
ml	d_7	h_9 max.	s_4
1	2 ± 0,5	32,5	0,7 ± 0,10
2		44,5	
3		46,5	
5		54,0	0,7 ± 0,15
10		70,0	0,8 ± 0,15
20		84,5	1 ± 0,20
25		99,5	
30		114,5	