



SLOVENSKI STANDARD SIST EN ISO 9187-1:2011

01-januar-2011

Nadomešča:
SIST EN ISO 9187-1:2008

Oprema za injiciranje za uporabo v medicini - 1. del: Ampule za parantalne farmacevtske oblike (ISO 9187-1:2010)

Injection equipment for medical use - Part 1: Ampoules for injectables (ISO 9187-1:2010)

Injektionsgeräte zur medizinischen Verwendung - Teil 1: Ampullen für Injektionspräparate (ISO 9187-1:2010)

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Matériel d'injection à usage médical - Partie 1: Ampoules pour produits injectables (ISO 9187-1:2010)

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Ta slovenski standard je istoveten z: EN ISO 9187-1:2010

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 9187-1

October 2010

ICS 11.040.20

Supersedes EN ISO 9187-1:2008

English Version

Injection equipment for medical use - Part 1: Ampoules for injectables (ISO 9187-1:2010)

Matériel d'injection à usage médical - Partie 1: Ampoules pour produits injectables (ISO 9187-1:2010)

Injektionsgeräte zur medizinischen Verwendung - Teil 1: Ampullen für Injektionspräparate (ISO 9187-1:2010)

This European Standard was approved by CEN on 13 October 2010.

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 CEN 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 CEN Management Centre has the same status as the official versions.

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

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Foreword

The text of ISO 9187-1:2010 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 9187-1:2010 by Technical Committee CEN/TC S02 “Transfusion equipment” the secretariat of which is held by CCMC.

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 April 2011, and conflicting national standards shall be withdrawn at the latest by April 2011.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 9187-1:2008.

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

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The text of ISO 9187-1:2010 has been approved by CEN as a EN ISO 9187-1:2010 without any modification.
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INTERNATIONAL
STANDARD

ISO
9187-1

Fourth edition
2010-10-15

**Injection equipment for medical use —
Part 1:
Ampoules for injectables**

Matériel d'injection à usage médical —

Partie 1: Ampoules pour produits injectables

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 9187-1 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This fourth edition cancels and replaces the third edition (ISO 9187-1:2006), which has undergone a minor revision with the following modifications in Table 1

— The base radius, r , has been modified for the 10 ml, 20 ml, 25 ml and 30 ml glass.

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*