



# SLOVENSKI STANDARD SIST EN ISO 8871-5:2014

01-oktober-2014

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## Deli iz elastomera za parenteralne farmacevtske oblike - 5. del: Funkcionalne zahteve in preskušanje (ISO 8871-5:2005)

Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 5: Functional requirements and testing (ISO 8871-5:2005)

Elastomere Teile für Parenteralia und für Geräte zur pharmazeutischen Verwendung - Teil 5: Funktionelle Anforderungen und Prüfung (ISO 8871-5:2005)

Éléments en élastomère pour administration parentérale et dispositifs à usage pharmaceutique - Partie 5: Exigences fonctionnelles et essais (ISO 8871-5:2005)

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**Ta slovenski standard je istoveten z: EN ISO 8871-5:2014**

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### **ICS:**

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment
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**SIST EN ISO 8871-5:2014**

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EUROPEAN STANDARD

EN ISO 8871-5

NORME EUROPÉENNE

EUROPÄISCHE NORM

July 2014

ICS 11.040.20

English Version

Elastomeric parts for parenterals and for devices for  
pharmaceutical use - Part 5: Functional requirements and testing  
(ISO 8871-5:2005)

Éléments en élastomère pour administration parentérale et  
dispositifs à usage pharmaceutique - Partie 5: Exigences  
fonctionnelles et essais (ISO 8871-5:2005)

Elastomere Teile für Parenteralia und für Geräte zur  
pharmazeutischen Verwendung - Teil 5: Funktionelle  
Anforderungen und Prüfung (ISO 8871-5:2005)

This European Standard was approved by CEN on 24 July 2014.

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-CENELEC 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-CENELEC 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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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## Foreword

The text of ISO 8871-5:2005 has been prepared by Technical Committee ISO/TC 76 “Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 8871-5:2014 by Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

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 January 2015, and conflicting national standards shall be withdrawn at the latest by January 2015.

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.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

### Endorsement notice

The text of ISO 8871-5:2005 has been approved by CEN as EN ISO 8871-5:2014 without any modification.

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# INTERNATIONAL STANDARD

**ISO**  
**8871-5**

First edition  
2005-08-15

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## Elastomeric parts for parenterals and for devices for pharmaceutical use —

### Part 5: Functional requirements and testing

*Éléments en élastomère pour administration parentérale et dispositifs à  
usage pharmaceutique —  
Partie 5: Exigences fonctionnelles et essais*

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## ISO 8871-5:2005(E)

## 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 8871-5 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This first edition of ISO 8871-5, together with ISO 8871-1, ISO 8871-2, ISO 8871-3 and ISO 8871-4, cancels and replaces ISO 8871:1990 and its Amendment 1:1995, which have been technically revised.

ISO 8871 consists of the following parts, under the general title *Elastomeric parts for parenterals and for devices for pharmaceutical use*:

- *Part 1: Extractables in aqueous autoclavates*
- *Part 2: Identification and characterization*
- *Part 3: Determination of released-particle count*
- *Part 4: Biological requirements and test methods*
- *Part 5: Functional requirements and testing*

## Introduction

Elastomeric or rubber closures for pharmaceutical use are used in combination with vials and many times in conjunction with piercing devices. There are three functional parameters which are important to the piercing process. These are: penetrability, fragmentation and self-sealing. The three functional tests described in this part of ISO 8871 can be used as a reference method for testing elastomeric closures that are pierced using injection needles made from metal. In addition, the container/closure seal integrity test can be used to verify the effectiveness of the sealing of a specific closure/vial combination.

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