SLOVENSKI STANDARD
SIST EN ISO 8871-5:2017

01-februar-2017

Nadomešča:
SIST EN ISO 8871-5:2014

Deli iz elastomera za parenteralne farmacevtske oblike - 5. del: Funkcionalne zahteve in preskušanje (ISO 8871-5:2016)

Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 5: Functional requirements and testing (ISO 8871-5:2016)

Elastomere Teile für Parenteralia und für Geräte zur pharmazeutischen Verwendung - Teil 5: Funktionelle Anforderungen und Prüfung (ISO 8871-5:2016)

Éléments en élastomère pour administration parentérale et dispositifs à usage pharmaceutique - Partie 5 : Exigences fonctionnelles et essais (ISO 8871-5:2016)

Ta slovenski standard je istoveten z: **EN ISO 8871-5:2016**

ICS:

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

SIST EN ISO 8871-5:2017 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8871-5

November 2016

ICS 11.040.20

Supersedes EN ISO 8871-5:2014

English Version

Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 5: Functional requirements and testing (ISO 8871-5:2016)

Éléments en élastomère pour administration parentérale et dispositifs à usage pharmaceutique - Partie 5: Exigences fonctionnelles et essais (ISO 8871-5:2016)

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This European Standard was approved by CEN on 6 August 2016.

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

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European foreword

This document (EN ISO 8871-5:2016) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use" in collaboration with 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of an identical text or by endorsement, at the latest by May 2017 and conflicting national standards shall be withdrawn at the latest by May 2017.

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.

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Endorsement notice

The text of ISO 8871-5:2016 has been approved by CEN as EN ISO 8871-5:2016 without any modification.

INTERNATIONAL STANDARD

ISO 8871-5

Second edition
2016-10-15

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

Reference number
ISO 8871-5:2016(E)

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 8871-5:2005), which has 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 aqueous solution tightness test can be used to verify the effectiveness of the sealing of a specific closure/vial combination.