SLOVENSKI STANDARD
SIST EN ISO 8871-5:2014

01-oktober-2014

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

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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)

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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of an identical text or by endorsement, at the latest by January 2015, and conflicting national standards shall be withdrawn at the latest by January 2015.

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Endorsement notice

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

INTERNATIONAL STANDARD

ISO 8871-5

First edition
2005-08-15

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

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Foreword

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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.

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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.