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

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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 8871-5:2014 sisaldab Euroopa standardi EN ISO 8871-5:2014 inglisekeelset teksti.	This Estonian standard EVS-EN ISO 8871-5:2014 consists of the English text of the European standard EN ISO 8871-5:2014.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 30.07.2014.	Date of Availability of the European standard is 30.07.2014.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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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)

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

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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of an identical text or by endorsement, at the latest by January 2015, and conflicting national standards shall be withdrawn at the latest by January 2015.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

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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.

Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 5: Functional requirements and testing

1 Scope

This part of ISO 8871 specifies requirements and test methods for functional parameters of elastomeric closures used in combination with vials and when pierced by an injection needle.

NOTE Functional testing with spikes is specified in ISO 8536-2 and in ISO 8536-6.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7864, *Sterile hypodermic needles for single use*

ISO 8362-1, *Injection containers and accessories — Part 1: Injection vials made of glass tubing*

ISO 8362-3, *Injection containers and accessories — Part 3: Aluminium caps for injection vials*

ISO 8362-4, *Injection containers and accessories — Part 4: Injection vials made of moulded glass*

ISO 8362-6, *Injection containers for injectables and accessories — Part 6: Caps made of aluminium-plastics combinations for injection vials*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
penetrability
force required for piercing an elastomeric closure

3.2
fragmentation
measure of the number of elastomeric particles which are generated by the piercing process

3.3
self-sealing
measure of the resealing efficiency of elastomeric closures following penetration and withdrawal of a needle