SVENSK STANDARD
SS-EN ISO 8871-5:2016

Fastställd/Approved: 2016-11-29
Publicerad/Published: 2016-12-06
Utgåva/Edition: 2
Språk/Language: engelska/English
ICS: 11.040.20

Elastomeriska delar avsedda för parenterala beredningar och för produkter för farmaceutiskt bruk – Del 5: Funktionella krav och provning (ISO 8871-5:2016)

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

This preview is downloaded from www.sis.se. Buy the entire standard via https://www.sis.se/std-8023818

This preview is downloaded from www.sis.se. Buy the entire standard via https://www.sis.se/std-8023818

Standarder får världen att fungera

SIS (Swedish Standards Institute) är en fristående ideell förening med medlemmar från både privat och offentlig sektor. Vi är en del av det europeiska och globala nätverk som utarbetar internationella standarder. Standarder är dokumenterad kunskap utvecklad av framstående aktörer inom industri, näringsliv och samhälle och befrämjar handel över gränser, bidrar till att processer och produkter blir säkrare samt effektiviserar din verksamhet.

Delta och påverka
Som medlem i SIS har du möjlighet att påverka framtida standarder inom ditt område på nationell, europeisk och global nivå. Du får samtidigt tillgång till tidig information om utvecklingen inom din bransch.

Ta del av det färdiga arbetet
Vi erbjuder våra kunder allt som rör standarder och deras tillämpning. Hos oss kan du köpa alla publikationer du behöver – allt från enskilda standarder, tekniska rapporter och standard-paket till handböcker och onlinetjänster. Genom vår webbtjänst e-nav får du tillgång till ett lättnavigerat bibliotek där alla standarder som är aktuella för ditt företag finns tillgängliga. Standarder och handböcker är källor till kunskap. Vi säljer dem.

Utveckla din kompetens och lyckas bättre i ditt arbete
Hos SIS kan du gå öppna eller företagsinterna utbildningar kring innehåll och tillämpning av standarder. Genom vår närhet till den internationella utvecklingen och ISO får du rätt kunskap i rätt tid, direkt från källan. Med vår kunskap om standarders möjligheter hjälper vi våra kunder att skapa verklig nytta och lönsamhet i sina verksamheter.

Vill du veta mer om SIS eller hur standarder kan effektivisera din verksamhet är du välkommen in på www.sis.se eller ta kontakt med oss på tel 08-555 523 00.

Standards make the world go round

SIS (Swedish Standards Institute) is an independent non-profit organisation with members from both the private and public sectors. We are part of the European and global network that draws up international standards. Standards consist of documented knowledge developed by prominent actors within the industry, business world and society. They promote cross-border trade, they help to make processes and products safer and they streamline your organisation.

Take part and have influence
As a member of SIS you will have the possibility to participate in standardization activities on national, European and global level. The membership in SIS will give you the opportunity to influence future standards and gain access to early stage information about developments within your field.

Get to know the finished work
We offer our customers everything in connection with standards and their application. You can purchase all the publications you need from us - everything from individual standards, technical reports and standard packages through to manuals and online services. Our web service e-nav gives you access to an easy-to-navigate library where all standards that are relevant to your company are available. Standards and manuals are sources of knowledge. We sell them.

Increase understanding and improve perception
With SIS you can undergo either shared or in-house training in the content and application of standards. Thanks to our proximity to international development and ISO you receive the right knowledge at the right time, direct from the source. With our knowledge about the potential of standards, we assist our customers in creating tangible benefit and profitability in their organisations.

If you want to know more about SIS, or how standards can streamline your organisation, please visit www.sis.se or contact us on phone +46 (0)8-555 523 00

This preview is downloaded from www.sis.se. Buy the entire standard via https://www.sis.se/std-8023818

Europastandarden EN ISO 8871-5:2016 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 8871-5:2016.

Denna standard ersätter SS-EN ISO 8871-5:2014, utgåva 1.

The European Standard EN ISO 8871-5:2016 has the status of a Swedish Standard. This document contains the official English version of EN ISO 8871-5:2016.

This standard supersedes the Swedish Standard SS-EN ISO 8871-5:2014, edition 1.

© Copyright/Upphovsrätten till denna produkt tillhör SIS, Swedish Standards Institute, Stockholm, Sverige. Användningen av denna produkt regleras av slutanvändarlicensen som återfinns i denna produkt, se standardens sista sidor.

© Copyright SIS, Swedish Standards Institute, Stockholm, Sweden. All rights reserved. The use of this product is governed by the end-user licence for this product. You will find the licence in the end of this document.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Förbrukningsmaterial inom sjukvården, SIS/TK 330.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

This preview is downloaded from www.sis.se. Buy the entire standard via https://www.sis.se/std-8023818

This preview is downloaded from www.sis.se. Buy the entire standard via https://www.sis.se/std-8023818

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)

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

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

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.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

© 2016 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

This preview is downloaded from www.sis.se. Buy the entire standard via https://www.sis.se/std-8023818

Contents

Page

This preview is downloaded from www.sis.se. Buy the entire standard via https://www.sis.se/std-8023818

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.

This document supersedes EN ISO 8871-5:2014.

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

This preview is downloaded from www.sis.se. Buy the entire standard via https://www.sis.se/std-8023818

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.

This preview is downloaded from www.sis.se. Buy the entire standard via https://www.sis.se/std-8023818

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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 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

3.4
aqueous solution tightness
measure for the effective sealing of a specific elastomeric closure/vial combination

This preview is downloaded from www.sis.se. Buy the entire standard via https://www.sis.se/std-8023818

4 Requirements

4.1 Penetrability

When tested in accordance with Annex A, the force required for piercing shall not be greater than 10 N for each closure.

4.2 Fragmentation

When tested in accordance with Annex B, the number of elastomeric fragments per 48 piercings visible with the naked eye shall not be greater than 5.

4.3 Self-sealing and aqueous solution tightness

When tested in accordance with Annex C, none of the vials shall contain any trace of coloured solution when observed with the naked eye. This requirement applies to multi-dose containers only, i.e. containers which utilize elastomeric closures that are pierced multiple times.

Materials that meet the requirements are not required to undergo further testing in accordance with 4.4.

4.4 Aqueous solution tightness

When tested in accordance with Annex D, none of the vials shall contain any trace of coloured solution when observed with the naked eye.

5 Preparation of elastomeric closures for testing

5.1 Sampling

The number of closures required for each test is as follows.

— Penetrability: 10

— Fragmentation: 12

— Self-sealing and aqueous solution tightness: 10

— Aqueous solution tightness: 10

In practice, it is recommended that more than the minimum required number of closures be prepared for testing.

5.2 Cleaning

Closures shall be sterilized in the as-delivered condition. If samples from regular production cleaning processes are not available, the stoppers shall be cleaned in accordance with the following procedure.

Introduce an appropriate number of rubber closures in a suitable glass container, cover with particle-free water, boil for 5 min, then rinse five times with cold particle-free water.

5.3 Sterilization

The closures shall be tested after having been subjected to the sterilization method actually used.

This preview is downloaded from www.sis.se. Buy the entire standard via https://www.sis.se/std-8023818

Annex A
(normative)

Test for penetrability

A.1 General

Many elastomeric closures for pharmaceutical use are used in conjunction with injection needles. The force necessary to penetrate or pierce a rubber closure is an important parameter in evaluating the suitability of the closure for its intended use.

A.2 Principle

The force necessary to completely pierce an elastomeric closure is measured using a suitable apparatus.

A.3 Apparatus, equipment and reagents

A.3.1 **10 closures**, prepared in accordance with Clause 5.

A.3.2 **10 clean vials**, in accordance with ISO 8362-1 or ISO 8362-4, neck finish size to match the size of closures (A.3.1) (e.g. 13 mm, 20 mm).

A.3.3 **10 aluminium or plastic/aluminium crimp seals**, in accordance with ISO 8362-3 or ISO 8362-6, sized to match the size of closures (A.3.1) (e.g. 13 mm, 20 mm), and crimping apparatus.

A.3.4 **10 lubricated long-bevel** [bevel angle (11 ± 2)°] **metal hypodermic needles**, external diameter of 0,8 mm in accordance with ISO 7864.

A.3.5 **Apparatus**, capable of measuring a force of 10 N with an accuracy of ±0,25 N.

A.4 Procedure

A.4.1 Close the vials (A.3.2) with the closures (A.3.1) to be tested and secure with a crimp seal (A.3.3).

A.4.2 Fit the force-measuring apparatus (A.3.5) with a hypodermic needle (A.3.4) and pierce a closure perpendicular to the surface. Record the maximum force. Use a new needle for each of the 9 remaining closures and repeat the procedure.

A.5 Expression of results

Record the force required for piercing each closure and compare the test results with the requirement in 4.1.