SVENSK STANDARD
SS-EN ISO 8871-5:2014

Fastställd/Approved: 2014-08-03
Publicerad/Published: 2014-08-20
Utgåva/Edition: 1
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 8871-5:2005)

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

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Europastandarden EN ISO 8871-5:2014 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 8871-5:2014.

The European Standard EN ISO 8871-5:2014 has the status of a Swedish Standard. This document contains the official version of EN ISO 8871-5:2014.

Förhållandet till övriga delar under samma huvudtitel - Utdrag ur Förord i ISO 8871-5:2005/ Relations to other parts under the same general title - Extract from the Foreword of ISO 8871-5:2005

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*

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.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8871-5

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.

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

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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.

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

3.4
container closure seal integrity
measure for the effective sealing of a specific elastomeric closure/vial combination

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 container closure seal integrity

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 multidose 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 Container closure seal integrity

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:

— penetrability 10

— fragmentation 12

— self-sealing and container closure seal integrity 10

— container closure seal integrity 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

Place the pretreated closures in a wide-necked flask and add enough of particle-free water to cover the closures. Cover the mouth of the flask with an inverted borosilicate-glass beaker or similar type closure. Heat in an autoclave so that a temperature of (121 ± 2) °C is reached within 20 min to 30 min and maintain at this temperature for 30 min. At the end of the autoclave cycle, remove the flask from the autoclave. Decant the water and allow the closures to dry.

Other sterilization methods, e.g. gamma sterilization or ethylene oxide sterilization, can have an influence on the functional properties. Their impact on the functional properties should therefore be evaluated accordingly.