SVENSK STANDARD
SS-EN ISO 8362-2:2015

Fastställd/Approved: 2015-11-02
Publicerad/Published: 2015-11-11
Utgåva/Edition: 2
Språk/Language: engelska/English
ICS: 11.040.20

Behållare för injektionsvätskor –
Del 2: Injektionsproppar till injektionsflaskor (ISO 8362-2:2015)

Injection containers and accessories –
Part 2: Closures for injection vials (ISO 8362-2:2015)

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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.

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Europastandarden EN ISO 8362-2:2015 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 8362-2:2015.

Denna standard ersätter SS-EN ISO 8362-2:2010, utgåva 1.

The European Standard EN ISO 8362-2:2015 has the status of a Swedish Standard. This document contains the official English version of EN ISO 8362-2:2015.

This standard supersedes the Swedish Standard SS-EN ISO 8362-2:2010, edition 1.

Förhållandet till övriga delar under samma huvudtitel - Utdrag ur Förord i ISO 8362-2:2015/
Relations to other parts under the same general title - Extract from the Foreword of ISO 8362-2:2015

ISO 8362 consists of the following parts, under the general title *Injection containers and accessories:*

- *Part 1: Injection vials made of glass tubing*
- *Part 2: Closures for injection vials*
- *Part 3: Aluminium caps for injection vials*
- *Part 4: Injection vials made of moulded glass*
- *Part 5: Freeze drying closures for injection vials*
- *Part 6: Caps made of aluminium-plastics combinations for injection vials*
- *Part 7: Injection caps made of aluminium-plastics combinations without overlapping plastics part*

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 8362-2

October 2015

ICS 11.040.20

Supersedes EN ISO 8362-2:2010

English Version

Injection containers and accessories - Part 2: Closures for injection vials (ISO 8362-2:2015)

Récipients et accessoires pour produits injectables - Partie 2 : Bouchons pour flacons (ISO 8362-2:2015)

Injektionsbehältnisse und Zubehör - Teil 2: Stopfen für Injektionsflaschen (ISO 8362-2:2015)

This European Standard was approved by CEN on 29 August 2015.

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

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European foreword

This document (EN ISO 8362-2:2015) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical and pharmaceutical use".

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 April 2016, and conflicting national standards shall be withdrawn at the latest by April 2016.

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 8362-2:2010.

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 8362-2:2015 has been approved by CEN as EN ISO 8362-2:2015 without any modification.

Introduction

The purpose of this part of ISO 8362 is to specify the shape and dimensions of, and the requirements for, elastomeric closures intended for pharmaceutical use. Closures made from elastomeric materials are suitable primary packaging materials for parenteral preparations. In order to provide seal integrity of the container closure systems, the dimensions of the elastomeric closures have to be compatible with the dimensions of the glass vials and the caps as specified in corresponding parts of ISO 8362.

Primary packaging components made of elastomeric materials are an integral part of medicinal products and thus the principles of current Good Manufacturing Practices (cGMP) apply to the manufacturing of these components.

Principles of cGMP are described in, for example, ISO 15378 or GMP Guidelines as published by the European Community and the United States of America.