SVENSK STANDARD
SS-EN ISO 8362-7:2010

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Behållare för injektionsvätskor –
Del 7: Aluminiumkapsyler med ej överlappande plastskiva till injektionsflaskor (ISO 8362-7:2006)

Injection containers and accessories –
Part 7: Injection caps made of aluminium-plastics combinations without overlapping plastics part (ISO 8362-7:2006)

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Europastandarden EN ISO 8362-7:2010 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 8362-7:2010.

The European Standard EN ISO 8362-7:2010 has the status of a Swedish Standard. This document contains the official English version of EN ISO 8362-7:2010.

Förhållandet till övriga delar under samma huvudtitel - Utdrag ur Förord i ISO 8362-7:2006/ Relations to other parts under the same general title - Extract from the Foreword of ISO 8362-7:2006

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.

Standarden 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 8362-7

December 2010

ICS 11.040.20

English Version

Injection containers and accessories - Part 7: Injection caps made of aluminium-plastics combinations without overlapping plastics part (ISO 8362-7:2006)

Récipients et accessoires pour produits injectables - Partie 7: Capsules d'injection en combinaison aluminium-plastique avec élément plastique non débordant (ISO 8362-7:2006)

Injektionsbehältnisse und Zubehör - Teil 7: Bördelkappen aus Aluminium-Kunststoffkombinationen für Injektionsflaschen ohne überstehendes Kunststoffteil (ISO 8362-7:2006)

This European Standard was approved by CEN on 21 November 2010.

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

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Ref. No. EN ISO 8362-7:2010: E

Foreword

The text of ISO 8362-7:2006 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 8362-7:2010 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 June 2011, and conflicting national standards shall be withdrawn at the latest by June 2011.

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Endorsement notice

The text of ISO 8362-7:2006 has been approved by CEN as a EN ISO 8362-7:2010 without any modification.

Introduction

The materials from which injection containers (including elastomeric closures) are made are suitable primary packaging materials for storing injectable products until they are administered. However, in this part of ISO 8362, injection caps are not considered as primary packaging materials in direct contact with pharmaceutical preparations.

During the processing of injection vials 2R and 4R, according to ISO 8362-1, and injection vials 6R, 8R, 10I, 5H, 7H and 8H, according to ISO 8362-1 and ISO 8362-4 respectively, difficulties may arise when using injection caps made of aluminium-plastics combinations corresponding to ISO 8362-6 because the diameter d_2 of the plastics element is larger than the diameter d of the injection vial body.

In order to avoid problems during the automatic working process, e.g. labelling of the vials or intermediate storage on a turntable, injection caps made of aluminium-plastics combinations are designed in such a way that the plastics element does not overlap the diameter of the vial body.