SLOVENSKI STANDARD
SIST EN ISO 8362-7:2011

01-marec-2011

Vsebniki za parenteralne farmacevtske oblike in dodatna oprema - 7. del: Pokrovček iz plastificiranega aluminija brez prekrivanja s plastičnim delom (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)

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

Ta slovenski standard je istoveten z: **EN ISO 8362-7:2010**

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

SIST EN ISO 8362-7:2011 **en**

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.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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

Contents

Page

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.

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.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

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

INTERNATIONAL STANDARD

ISO 8362-7

Second edition
2006-04-15

Injection containers and accessories —

Part 7: Injection caps made of aluminium-plastics combinations without overlapping plastics part

Récipients et accessoires pour produits injectables —

Partie 7: Capsules d'injection en combinaison aluminium-plastique avec élément plastique non débordant

Reference number
ISO 8362-7:2006(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 8362-7 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 8362-7:1995), of which it constitutes a minor revision.

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*