

**Injection containers and accessories - Part 6: Caps
made of aluminium-plastics combinations for injection
vials (ISO 8362-6:2010)**

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 8362-6:2011 sisaldab Euroopa standardi EN ISO 8362-6:2011 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 31.05.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 27.04.2011.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO 8362-6:2011 consists of the English text of the European standard EN ISO 8362-6:2011.

This standard is ratified with the order of Estonian Centre for Standardisation dated 31.05.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

Date of Availability of the European standard text 27.04.2011.

The standard is available from Estonian standardisation organisation.

ICS 11.040.20

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English Version

**Injection containers and accessories - Part 6: Caps made of
aluminium-plastics combinations for injection vials (ISO 8362-
6:2010)**

Réipients et accessoires pour produits injectables - Partie
6: Capsules pour flacons d'injection fabriquées en un
mélange aluminium-plastique (ISO 8362-6:2010)

Injektionsbehälter und Zubehör - Teil 6: Bördekappen
aus Aluminium-Kunststoffkombinationen für
Injektionsflaschen (ISO 8362-6:2010)

This European Standard was approved by CEN on 24 March 2011.

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

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Foreword

The text of ISO 8362-6:2010 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 8362-6:2011 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 October 2011, and conflicting national standards shall be withdrawn at the latest by October 2011.

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Endorsement notice

The text of ISO 8362-6:2010 has been approved by CEN as a EN ISO 8362-6:2011 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, caps are not considered as primary packaging materials in direct contact with pharmaceutical preparations.

Injection containers and accessories —

Part 6:

Caps made of aluminium-plastics combinations for injection vials

1 Scope

This part of ISO 8362 specifies caps made of aluminium-plastics combinations for injection vials as specified in ISO 8362-1 and ISO 8362-4.

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 2768-1, *General tolerances — Part 1: Tolerances for linear and angular dimensions without individual tolerance indications*

ISO 2768-2, *General tolerances — Part 2: Geometrical tolerances for features without individual tolerance indications*

ISO 8362-3, *Injection containers and accessories — Part 3: Aluminium caps for injection vials*

ISO 8872:2003, *Aluminium caps for transfusion, infusion and injection bottles — General requirements and test methods*

ISO 10985, *Caps made of aluminium-plastics combinations for infusion bottles and injection vials — Requirements and test methods*

3 Classification of types

Caps shall be classified as follows:

- Type ZB: aluminium cap with central opening and plastics component;
- Type ZD: aluminium cap with complete tear-off tab and plastics component.