

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 8362-7:2010 sisaldab Euroopa standardi EN ISO 8362-7:2010 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 31.12.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 08.12.2010.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO 8362-7:2010 consists of the English text of the European standard EN ISO 8362-7:2010.

This standard is ratified with the order of Estonian Centre for Standardisation dated 31.12.2010 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

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English Version

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

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

Injektionsbehälter 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.

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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 8362-7:2006 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of an identical text or by endorsement, at the latest by June 2011, and conflicting national standards shall be withdrawn at the latest by June 2011.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.

Injection containers and accessories —

Part 7:

Injection caps made of aluminium-plastics combinations without overlapping plastics part

1 Scope

This part of ISO 8362 specifies aluminium-plastics combinations for the injection caps of injection vials, as specified in ISO 8362-1 and ISO 8362-4, where the plastics part does not overlap the diameter of the vial body.

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 7500-1, *Metallic materials — Verification of static uniaxial testing machines — Part 1: Tension/compression testing machines — Verification and calibration of the force-measuring system*

ISO 8362-1:2003, *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 8362-4:2003, *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*

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

3 Classification of types

Injection caps shall be classified as follows:

- Type OB: Aluminium cap with central opening, and without overlapping plastics component;
- Type OD: Aluminium cap with complete tear-off tab, and without overlapping plastics component.