Injection containers and accessories - Part 3: Aluminium caps for injection vials

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EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 8362-3:2003 sisaldab Euroopa standardi EN ISO 8362-3:2003 ingliskeelset teksti. Käesolev dokument on jõustatud 06.06.2003 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 8362-3:2003 consists of the English text of the European standard EN ISO 8362-3:2003. This document is endorsed on 06.06.2003 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This part of ISO 8362specifies aluminium caps for injection vials as described in ISO 8362-1 and ISO 8362-4	**Scope:** This part of ISO 8362specifies aluminium caps for injection vials as described in ISO 8362-1 and ISO 8362-4

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Võtmesõnad: closing devices, injection bo, injection containers, injection instruments, injections, knurled caps, marking, medical equipment, medical sciences, medicine, packages, packing, parenteral infusion equipment, products, shape, specification (approval), specifications

EUROPEAN STANDARD

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EN ISO 8362-3

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English version

Injection containers and accessories
Part 3: Aluminium caps for injection vials
(ISO 8362-3:2001)

Récipients et accessoires pour produits injectables —
Partie 3: Capsules en aluminium pour flacons
(ISO 8362-3:2001)

Injektionsbehältnisse für Injektionspräparate und Zubehör —
Teil 3: Aluminium-Bördelkappen für Injektionsflaschen
(ISO 8362-3:2001)

This European Standard was approved by CEN on 27 December 2002.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovak Republic, Spain, Sweden, Switzerland and United Kingdom.

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

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Contents

Foreword

The text of ISO 8362-3:2001 has been prepared by Technical Committee ISO/TC 76 “Transfusion, infusion and injection equipment for medical and pharmaceutical use” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 8362-3:2003 by CMC.

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 *August 2003*, and conflicting national standards shall be withdrawn at the latest by *August 2003*.

This document supersedes EN 28362-3:1993.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 8362-3:2001 has been approved by CEN as EN ISO 8362-3:2003 without any modifications.

NOTE Normative references to International Standards are listed in Annex ZA (normative).

Introduction

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

1 Scope

This part of ISO 8362 specifies aluminium caps for injection vials as described in ISO 8362-1 and ISO 8362-4.

2 Normative references

The following normative document contains provisions which, through reference in this text, constitute provisions of this part of ISO 8362. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 8362 are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

3 Dimensions and designation

3.1 Dimensions

The dimensions of aluminium caps shall be as shown in Figure 1 and as given in Table 1.

3.2 Designation

Aluminium caps are designated according to type: the four types A, B, C and D are illustrated in Figure 1. The designation is expressed as the number and part of this International Standard, followed by the nominal size of the container, followed by the type letter.

EXAMPLE A type B (i.e. two-bridge tab) aluminium cap (B) of nominal size 13 complying with the requirements laid down in this part of ISO 8362 is designated.

Aluminium cap ISO 8362-3-13-B

4 Requirements

4.1 General

The caps shall meet the requirements of ISO 8872.

4.2 Force required to remove tab

4.2.1 Two- or three-bridge tabs (types B and C)

The force needed to remove the tab shall be determined in accordance with ISO 8872 and shall be within the range given in Table 2.

4.2.2 Complete tear-off tab (type D)

The force needed to remove the tab completely shall be determined in accordance with ISO 8872 and shall be within the range given in Table 3.