

Infusion equipment for medical use - Part 3: Aluminium caps for infusions bottles

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 8536-3:2009 sisaldab Euroopa standardi EN ISO 8536-3:2009 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 30.11.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 01.06.2009.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO 8536-3:2009 consists of the English text of the European standard EN ISO 8536-3:2009.

This standard is ratified with the order of Estonian Centre for Standardisation dated 30.11.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

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ICS 11.040.20

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EUROPEAN STANDARD

EN ISO 8536-3

NORME EUROPÉENNE

EUROPÄISCHE NORM

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Supersedes EN ISO 8536-3:1999

English Version

Infusion equipment for medical use - Part 3: Aluminium caps for infusion bottles (ISO 8536-3:2009)

Matériel de perfusion à usage médical - Partie 3: Capsules en aluminium pour flacons de perfusion (ISO 8536-3:2009)

Infusionsgeräte zur medizinischen Verwendung - Teil 3: Aluminium-Bördelkappen für Infusionsflaschen (ISO 8536-3:2009)

This European Standard was approved by CEN on 16 May 2009.

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

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Foreword

This document (EN ISO 8536-3:2009) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical and pharmaceutical use" in collaboration with CEN Sub-sector S02 "Transfusion equipment", the secretariat of which is held 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of an identical text or by endorsement, at the latest by December 2009, and conflicting national standards shall be withdrawn at the latest by December 2009.

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Endorsement notice

The text of ISO 8536-3:2009 has been approved by CEN as a EN ISO 8536-3:2009 without any modification.

Introduction

The materials from which infusion glass bottles (including elastomeric closures) are made are suitable primary packaging materials for storing infusion solutions until they are administered. However, in this part of ISO 8536, aluminium caps are not considered as primary packaging material in direct contact with the infusion solution.

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Infusion equipment for medical use —

Part 3:

Aluminium caps for infusion bottles

1 Scope

This part of ISO 8536 specifies aluminium caps for infusion glass bottles which are in accordance with ISO 8536-1.

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 8536-1, *Infusion equipment for medical use — Part 1: Infusion glass bottles*

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

3 Dimensions and tolerances

3.1 Dimensions

The dimensions of the caps shall be as shown in Figures 1 to 3 and as given in Table 1.

The shapes of the caps are shown only as typical examples.

The components of a two-piece tear-off cap are:

- an aluminium cap with centre hole, type A;
- a protective aluminium cap with complete tear-off tab, type F.

The components of a three-piece tear-off cap are:

- an aluminium cap with centre hole, type A;
- a protective disc, E;
- a protective aluminium cap with complete tear-off tab, type F.

NOTE The width and the number of bridges for types C and F are a function of the intended resistance.