EESTI STANDARD EVS-EN ISO 8536-3:2001

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

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 8536-3:2001 sisaldab Euroopa standardi EN ISO 8536-3:1999+AC:1999 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 8536-3:2001 consists of the English text of the European standard EN ISO 8536-3:1999+AC:1999.
Standard on kinnitatud Eesti Standardikeskuse 18.06.2001 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 18.06.2001 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 23.040.60

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8536-3

February 1999

ICS 11.040.20

English version

Infusion equipment for medical use - Part 3: Aluminium caps for infusion bottles (ISO 8536-3:1999)

Matériel de perfusion à usage médical - Partie 3: Capsules en aluminium pour flacons de perfusion (ISO 8536-3:1999)

Infusionsgeräte zur medizinischen Verwendung - Teil 3: Aluminium-Bördelkappen für Infusionsflaschen (ISO 8536-3:1999)

This European Standard was approved by CEN on 25 January 1999.

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 Central Secretariat 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 Central Secretariat 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, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Foreword

Corrected 1999-10-28

The text of the International Standard from Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical use" of the International Organization for Standardization (ISO) has been taken over as an European Standard by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by BSI.

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 1999, and conflicting national standards shall be withdrawn at the latest by August 1999.

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, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 8536-3:1992 has been approved by CEN as a European Standard without any modification.

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

Annex A (informative)

A-deviations

A-deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of CEN/CENELEC member:

This European Standard falls under Directive 93/42/EEC.

NOTE (from CEN/CENELEC IR Part 2, **3.1.9**): Where standards fall under EC Directives it is the view of the Commission of the European Communities (OJ No G 59, 9.3, 1982) that the effect of the decision of the Court of Justice in case 815/79 Cremonini/Vrankovitch (European Court Reports 1980, p.3583) is that compliance with A-deviations is no longer mandatory and that the free movement of products complying with such a standard should not be restricted except under the safeguard procedure provided for in the relevant Directive.

A-deviations in an EFTA country are valid instead of the relevant provisions of the European Standard in that country until they have been removed.

The European Standard is not in agreement with the European Pharmacopoeia 2nd edition VI.2.3.1, which is mandatory in Sweden, by LVFS 1996:16.

Annex ZA (normative)
Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Publication	Year	Title	EN	Year
ISO 2768-1	1989	General tolerances - Part 1: Tolerances for linear and angular dimensions without individual tolerance indications	EN 22768-1	1993
ISO 2768-2	1989	General tolerances - Part 2: Geometrical tolerances for features without individual tolerance indications	EN 22768-2	1993
ISO 8536-1	1999	Infusion equipment for medical use - Part 1: Infusion glass bottles	EN ISO 8536-1	1999
ISO 8872	1988	Aluminium caps for transfusion, infusion and injection bottles - General requirements and test methods	EN 28872	1993

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8536-3:1999/AC

May 1999
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English version
Version Française
Deutsche Fassung

Infusion equipment for medical use - Part 3: Aluminium caps for infusion bottles (ISO 8536-3:1992)

Matériel de perfusion à usage médical - Partie 3: Capsules en aluminium pour flacons de perfusion (ISO 8536-3:1992)

Infusionsgeräte zur medizinischen Verwendung - Teil 3: Aluminium-Bördelkappen für Infusionsflaschen (ISO 8536-3:1992)

This corrigendum becomes effective on 14 May 1999 for incorporation in the three official language versions of the EN.

Ce corrigendum prendra effet le 14 mai 1999 pour incorporation dans les trois versions linguistiques officielles de l'EN.

Die Berichtigung tritt am 14.Mai 1999 zur Einarbeitung in die drei offiziellen Sprachfassungen der EN in Kraft.

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 8536-3:1999/AC:1999 D/I

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Endorsement notice

The text of the International Standard ISO 8536-3:1992 has been approved by CEN as a European Standard without any modification.

INTERNATIONAL STANDARD

ISO 8536-3

Second edition
1999-09-01

Infusion equipment for medical use —

Part 3:

Aluminium caps for infusion bottles

Matériel de perfusion à usage médical

Partie 3: Capsules en aluminium pour flacons de perfusion

Reference number
ISO 8536-3:1999(E)

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 3.

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 part of ISO 8536 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 8536-3 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 8536-3:1992), which has been technically revised.

ISO 8536 consists of the following parts, under the general title *Infusion equipment for medical use*:

— *Part 1: Infusion glass bottles*

— *Part 2: Closures for infusion bottles*

— *Part 3: Aluminium caps for infusion bottles*

— *Part 4: Infusion sets for single use, gravity feed*

— *Part 5: Burette-type infusion sets*

— *Part 6: Freeze-drying closures for infusion bottles*

— *Part 7: Caps made of aluminium-plastics combinations for infusion bottles*

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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.

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 normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 8536. 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 8536 are encouraged to investigate the possibility of applying the most recent editions of the normative documents 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 2768-1:—[1)], *Geometrical product specifications (GPS) — General tolerances — Part 1: Tolerances for linear and angular dimensions without individual tolerance indications*.

ISO 2768-2:1989, *General tolerances — Part 2: Geometrical tolerances for features without individual tolerance indications.*

ISO 8536-1:1991, *Infusion equipment for medical use — Part 1: Infusion glass bottles.*

ISO 8872:1988, *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;

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1) To be published. (Revision of ISO 2768-1:1989)