Aluminium caps and aluminium/plastic caps for infusion bottles and injection vials - General requirements and test methods (ISO 8872:2022)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 8872:2022 sisaldab Euroopa standardi EN ISO 8872:2022 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 8872:2022 consists of the English text of the European standard EN ISO 8872:2022.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 23.11.2022.	Date of Availability of the European standard is 23.11.2022.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

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English Version

Aluminium caps and aluminium/plastic caps for infusion bottles and injection vials - General requirements and test methods (ISO 8872:2022)

Capsules en aluminium et capsules en aluminium/plastique pour flacons de perfusion et d'injection - Exigences générales et méthodes d'essai (ISO 8872:2022)

Aluminium- und Aluminium/Kunststoff-Bördelkappen für Infusions- und Injektionsflaschen - Allgemeine Anforderungen und Prüfverfahren (ISO 8872:2022)

This European Standard was approved by CEN on 20 March 2022.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 8872:2022) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use" in collaboration with CCMC.

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of an identical text or by endorsement, at the latest by May 2023, and conflicting national standards shall be withdrawn at the latest by May 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 8872:2003.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 8872:2022 has been approved by CEN as EN ISO 8872:2022 without any modification.

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/SS S02, *Transfusion equipment,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 8872:2003) and ISO 10985:2009, which have been technically revised.

The main changes are as follows:

— integration of ISO 10985;

— addition of new terms;

— addition of a new Annex A, "Aluminium and aluminium plastic caps - Type drawings";

— addition of a new Annex B, "Opening and tear-off forces".

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The primary materials from which containers, including their elastomeric closures, are made must be suitable for the storage of such products until the products are administered. However, in this document, aluminium caps and aluminium/plastic caps are not considered as primary packaging materials that will come into direct contact with pharmaceutical preparations. Aluminium and aluminium/plastic caps can be delivered to customers as non-sterile products or as sterile products.

Aluminium caps and aluminium/plastic caps for infusion bottles and injection vials — General requirements and test methods

1 Scope

This document specifies general requirements and test methods for aluminium caps and aluminium/plastic caps intended for use on infusion bottles and/or injection vials.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 6892-1, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

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

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

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

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

ISO 8536-3, *Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles*

ISO 8536-7, *Infusion equipment for medical use — Part 7: Caps made of aluminium-plastics combinations for infusion bottles*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
coating
surface lacquer or polymer layer on the aluminium part of the cap

Note 1 to entry: The coating allows for better processing and product differentiation.

3.2
crimping
act of fixating the aluminium or aluminium/plastic cap over the rubber stopper and under the neck of a bottle or vial, such that the stopper is held firmly in place, thereby securing the container/closure integrity of the bottle or vial system