SLOVENSKI STANDARD
oSIST prEN ISO 8872:2022

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Aluminijeve in aluminijeve/plastične zaporke za infuzijske in injekcijske steklenice - Splošne zahteve in preskusne metode (ISO/DIS 8872:2021)

Aluminium caps and aluminium/plastic caps for infusion bottles and injection vials - General requirements and test methods (ISO/DIS 8872:2021)

Aluminium- und Aluminium/Kunststoff-Bördelkappen für Infusions- und Injektionsflaschen - Allgemeine Anforderungen und Prüfverfahren (ISO/DIS 8872:2021)

Capsules en aluminium et capsules en aluminium/plastique pour flacons de perfusion et d'injection - Exigences générales et méthodes d'essai (ISO/DIS 8872:2021)

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

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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.*

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

The main changes compared to the previous edition are as follows:

— integration of ISO 10985 into ISO 8872;

— conversion to the present ISO standard format.

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

This International Standard specifies requirements for aluminium caps and for aluminium/plastic caps for bottles and vials in the field of infusion and injection. The primary materials from which containers, including their elastomeric closures, are made have to be suitable for the storage of such products until the products are administered. However, in this International Standard, 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 International Standard 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 terminological 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
the 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 container/closure integrity of the bottle or vial system.

3.3
earing
degree of undulation (waviness) of the processed edge of an aluminum cap

3.4
tear-off tab
all aluminium seal with a tear tab that allows prior-to-use removal of the ferrule that is scored on its skirt

Note 1 to entry: For a drawing, see ISO 8536-3.

4 Requirements

For type drawings of aluminium and aluminium/plastic caps, reference is made to Annex A.

Aluminium and aluminium/plastic caps can be delivered to customers as non-sterile products or as sterile products. Specific requirements regarding e.g packaging and specifications of sterile caps shall be agreed upon between supplier and customer.

4.1 Aluminium component

4.1.1 Mechanical characteristics

The mechanical characteristics of the aluminium alloy shall comply with the requirements specified for the three grades A, B or C (see Table 1) and shall be tested in accordance with the test procedures described in 5.2.

Table 1 — Grades of mechanical characteristics

Grade	Alloy[a]	Tensile strength R_m N/mm²		Proof stress of non-proportional elongation R_p N/mm²
		min.	max.	min.
A	AlFeSi annealed or coated	100	150	80
B	AlFeSi	130	170	110
C	AlMnCu	140	180	120

[a] These alloys present a selection of widely used aluminium alloys for manufacture of caps. Other alloys are permitted, provided that they otherwise meet the requirements in this table.

4.1.2 Chemical composition

The aluminium component of the cap shall be produced from aluminium alloy as described in Table 1. Aluminium used for caps is coated at its surface with a suitable surface layer, typically a lacquer or polymer layer.

The chemical composition of the aluminium shall be verified in accordance with 5.3.

4.1.3 Dimensions

Aluminium components shall comply with the dimensions and with the accepted tolerances as specified in the relevant International Standards as listed in Clause 2.

The thickness shall be measured in accordance with the test method in 5.4.

4.1.4 Contamination

Aluminium components shall be free from contamination from the manufacturing process; the presence of residual lubricants shall be reduced to an absolute minimum.

4.1.5 Earing

Aluminium components should be free from earing defects at the cutting processing edge. If earing occurs, the earing defect, as measured in accordance with 5.5, shall not be greater than 3 %.

4.1.6 Other defects

Burrs and bite marks shall be avoided in manufacturing of aluminium components.

4.2 Plastic component

4.2.1 Mechanical characteristics

The plastic component of caps that are intended for steam sterilization shall be steam-sterilizable at 121 °C for 30 min. The material shall withstand a temperature of 130 °C for a short time (max. 5 min).

The plastic component of caps that are intended for irradiation sterilization shall withstand a representative irradiation cycle without change of mechanical characteristics, such as brittleness, that could have an impact on the functional requirements of the cap.

4.2.2 Chemical composition

The plastic material shall meet the current regulations for use in non-contact pharmaceutical components.

NOTE For further information, see ISO 10993-18.

4.2.3 Dimensions

Plastic components shall comply with the dimensions and with the accepted tolerances for the corresponding size as specified in the relevant International Standards as listed in Clause 2.

4.2.4 Contamination

Plastic components shall be free from contamination from the manufacturing process.

4.2.5 Other defects

The plastic component shall not have sharp edges or non-permissible protruding moulding flash.

4.3 Functional requirements of aluminium and aluminium-plastic caps

4.3.1 Opening and tear-off forces for aluminium caps

When measured in accordance with the test method described in 5.6, the forces needed to remove the tabs or to tear them off completely shall comply with the limits for the corresponding size specified in the relevant International Standards as described in Clause 2.

During removal, the complete tear-off tab shall be torn off only as determined by the score path.

When the test in accordance with 5.6 is carried out, no parts of aluminium caps shall break except the bridges and score paths.