

SLOVENSKI STANDARD

SIST EN ISO 8872:2023

01-februar-2023

Nadomešča:

SIST EN ISO 8872:2003

Aluminijeve in aluminijeve/plastične zaporke za infuzijske in injekcijske steklenice - Splošne zahteve in preskusne metode (ISO 8872:2022)

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

Aluminium- und Aluminium/Kunststoff-Bördelkappen für Infusions- und Injektionsflaschen
- Allgemeine Anforderungen und Prüfverfahren (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)

Ta slovenski standard je istoveten z: EN ISO 8872:2022

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment
77.150.10	Aluminijski izdelki	Aluminium products

SIST EN ISO 8872:2023

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 8872

November 2022

ICS 11.040.20

Supersedes EN ISO 8872:2003

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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents	Page
European foreword.....	3

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of an identical text or by endorsement, at the latest by May 2023, and conflicting national standards shall be withdrawn at the latest by May 2023.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

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Endorsement notice

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

INTERNATIONAL STANDARD

**ISO
8872**

Third edition
2022-11

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

*Capsules en aluminium et capsules en aluminium/plastique pour
flacons de perfusion et d'injection — Exigences générales et méthodes
d'essai*

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Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements	2
4.1 General	2
4.2 Aluminium component	2
4.2.1 Mechanical characteristics	2
4.2.2 Chemical composition	2
4.2.3 Dimensions	3
4.2.4 Contamination	3
4.2.5 Earing	3
4.2.6 Other defects	3
4.3 Plastic component	3
4.3.1 Mechanical characteristics	3
4.3.2 Chemical composition	3
4.3.3 Dimensions	3
4.3.4 Contamination	3
4.3.5 Other defects	3
4.4 Functional requirements of aluminium and aluminium-plastic caps	4
4.4.1 Opening and tear-off forces for aluminium caps	4
4.4.2 Joining of aluminium and plastic component	4
4.4.3 Opening and tear-off forces for aluminium/plastic caps	4
4.4.4 Mechanical requirements after sterilization	4
5 Test methods	4
5.1 General	4
5.2 Mechanical characteristics	5
5.3 Chemical composition	5
5.4 Dimensions	5
5.5 Earing	5
5.6 Opening and tear-off forces of aluminium and aluminium/ plastic caps	5
5.7 Test methods after sterilization	6
5.7.1 Stability of coating on aluminium	6
5.7.2 Test method for premature opening and deformation	6
6 Packaging	6
7 Marking	6
Annex A (informative) Aluminium and aluminium plastic caps – Type drawings	7
Annex B (normative) Opening and tear-off forces	8
Bibliography	13

ISO 8872:2022(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.

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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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.

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