



# SLOVENSKI STANDARD

## SIST EN 28872:2000

01-januar-2000

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### Aluminijeve zaporke za transfuzijske, infuzijske in injekcijske steklenice - Splošne zahteve in preskusne metode (ISO 8872:1988)

Aluminium caps for transfusion, infusion and injection bottles - General requirements and test methods (ISO 8872:1988)

Aluminium-Bördelkappen für Transfusions-, Infusions- und Injektionsflaschen - Allgemeine Anforderungen und Prüfverfahren (ISO 8872:1988)

Capsules en aluminium pour flacons de transfusion, perfusion et injection - Spécifications générales et méthodes d'essai (ISO 8872:1988)

<https://standards.iteh.ai/catalog/standards/sist/02ab4c92-e0d3-4e15-8644->

Ta slovenski standard je istoveten z: **EN 28872:1993**

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#### **ICS:**

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment
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**SIST EN 28872:2000**

**en**

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EUROPEAN STANDARD

EN 28872:1993

NORME EUROPÉENNE

EUROPÄISCHE NORM

April 1993

UDC 615.473:621.798.26-034.71:620.1

Descriptors: Medical equipment, perfusion equipment, blood transfusion equipment, injectable products, flasks, caps: containers, aluminium products, specifications, tests, marking

English version

**Aluminium caps for transfusion, infusion and  
injection bottles - General requirements and test  
methods (ISO 8872:1988)**

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Capsules en aluminium pour flacons de transfusion, perfusion et injection. Spécifications générales et méthodes d'essai (ISO 8872:1988)

Aluminium-Bördelkappen für Transfusions-, Infusions- und Injektionsflaschen - Allgemeine Anforderungen und Prüfverfahren (ISO 8872:1988)

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This European Standard was approved by CEN on 1993-04-14. 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.

The European Standards exist 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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

**CEN**

European Committee for Standardization  
Comité Européen de Normalisation  
Europäisches Komitee für Normung

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

## Foreword

In 1990, the International Standard ISO 8872:1988 "Aluminium caps for transfusion, infusion and injection bottles - General requirements and test methods" was submitted to the CEN Primary Questionnaire procedure.

Following the positive result of the CEN/CS Proposal, ISO 8872:1988 was submitted to the Formal Vote.

The result of the Formal Vote was positive.

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 October 1993, and conflicting national standards shall be withdrawn at the latest by October 1993.

According to the CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom.

## Endorsement notice

The text of the International Standard ISO 8872:1988 was approved by CEN as a European Standard without any modification.

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# INTERNATIONAL STANDARD

ISO  
8872

First edition  
1988-12-15



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INTERNATIONAL ORGANIZATION FOR STANDARDIZATION  
ORGANISATION INTERNATIONALE DE NORMALISATION  
МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

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## Aluminium caps for transfusion, infusion and injection bottles — General requirements and test methods

*Capsules en aluminium pour flacons de transfusion, perfusion et injection — Spécifications générales et méthodes d'essai*

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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 8872 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use*.

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Annex A of this International Standard is for information only.

## Introduction

This International Standard specifies requirements in general for aluminium caps for vials and bottles in the field of transfusion, 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 are not considered as primary packaging materials that will come into direct contact with pharmaceutical preparations or blood.

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# Aluminium caps for transfusion, infusion and injection bottles — General requirements and test methods

## 1 Scope

This International Standard specifies general requirements and test methods for aluminium caps for injection vials, and infusion and transfusion bottles.

## 2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 6892 : 1984, *Metallic materials — Tensile testing*.

ISO 7500-1 : 1986, *Metallic materials — Verification of static uniaxial testing machines — Part 1: Tensile testing machines*.

## 3 Requirements

### 3.1 Wrought products

#### 3.1.1 Mechanical characteristics

The mechanical characteristics shall comply with the requirements specified for the three grades A, B and C (see table 1) and shall be tested in accordance with the test procedures described in 4.2.

Table 1 — Grades of mechanical characteristics

Grade	Alloy <sup>1)</sup>	Tensile strength		Proof stress of non-proportional elongation $R_p$ N/mm <sup>2</sup> min.
		$R_m$ N/mm <sup>2</sup> min.	max.	
A	AlFeSi annealed or coated	100	150	80
B	AlFeSi	130	170	110
C	AlMnCu	140	180	120

1) 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 the table -

### 3.1.2 Chemical composition

The wrought (sheet and strip) used for the manufacture of caps shall be produced from aluminium alloy.

NOTE — The chemical composition of widely used aluminium alloys is given as an example in annex A.

The chemical composition shall be checked in accordance with 4.3.

## 3.2 Caps

### 3.2.1 Dimensions

Aluminium caps shall comply with the dimensions and with the accepted tolerances as specified in the pertinent International Standards.

The thickness shall be measured in accordance with 4.4.

### 3.2.2 Contamination

Aluminium caps shall be free from contamination; the presence of residual lubricants and burrs shall be avoided.

### 3.2.3 Earing

Aluminium caps should be free from earing defects at the cutting processing edge. If earing occurs, the earing defect, as measured in accordance with 4.5, shall not be greater than 3 %.

### 3.2.4 Crimping

Aluminium caps shall fit properly when subjected to the crimping process as described in 4.6.

### 3.2.5 Resistance of caps

3.2.5.1 When tested in accordance with 5.2, the aluminium caps, put in place by a crimping process as described in 4.6, shall not show ruptures or important signs of deformation.

NOTE — This requirement only applies to caps that will be subject to sterilization.

3.2.5.2 When measured in accordance with the test methods described in 4.7 and 4.8, the forces needed to remove the tabs