INTERNATIONAL STANDARD

ISO 8872

Second edition
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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 8872 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 8872:1988), which has been technically revised.

Introduction

This International Standard specifies requirements 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.

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 for infusion and transfusion bottles.

2 Normative references

The following referenced documents are indispensable for the application 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 6892:1998, *Metallic materials — Tensile testing at ambient temperature*

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

ISO 8362-3:2001, *Injection containers and accessories — Part 3: Aluminium caps for injection vials*

ISO 8536-3:1999, *Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles*

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 or C (see Table 1) and shall be tested in accordance with the test procedures described in 4.2.