SLOVENSKI STANDARD
SIST EN ISO 8871-2:2005

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Deli iz elastomera za parenteralne farmacevtske oblike - 2. del: Identifikacija in opredelitev (ISO 8871-2:2003)

Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 2: Identification and characterization (ISO 8871-2:2003)

Elastomere Teile für Parenteralia und für Geräte zur pharmazeutischen Verwendung - Teil 2: Identifizierung und Charakterisierung (ISO 8871-2:2003)

Eléments en élastomere pour administration parentérale et dispositifs a usage pharmaceutique - Partie 2: Identification et caractérisation (ISO 8871-2:2003)

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11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

SIST EN ISO 8871-2:2005 **en**

EUROPEAN STANDARD

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English version

Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 2: Identification and characterization (ISO 8871-2:2003)

Eléments en élastomère pour administration parentérale et dispositifs à usage pharmaceutique - Partie 2: Identification et caractérisation (ISO 8871-2:2003)

This European Standard was approved by CEN on 15 July 2004.

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.

This European Standard exists 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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

The text of ISO 8871-2:2003 has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical and pharmaceutical use" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 8871-2:2004 by CMC.

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 March 2005, and conflicting national standards shall be withdrawn at the latest by March 2005.

This document supersedes EN ISO 8871:1997.

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

Endorsement notice

The text of ISO 8871-2:2003 has been approved by CEN as EN ISO 8871-2:2004 without any modifications.

INTERNATIONAL STANDARD

ISO 8871-2

First edition
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Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 2: Identification and characterization

Éléments en élastomère pour administration parentérale et dispositifs à usage pharmaceutique —

Partie 2: Identification et caractérisation

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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 8871-2 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

Together with the other parts (see below), this part of ISO 8871 cancels and replaces ISO 8871:1990, which has been technically revised.

ISO 8871 consists of the following parts, under the general title *Elastomeric parts for parenterals and for devices for pharmaceutical use*:

— *Part 1: Extractables in aqueous autoclavates*

— *Part 2: Identification and characterization*

— *Part 3: Determination of released-particle count*

— *Part 4: Biological requirements and test methods*

— *Part 5: Functional requirements and testing*

Introduction

The elastomeric parts specified in the various parts of this International Standard are produced from a material which is usually called “rubber”. However, rubber is not a unique entity, since the composition of rubber materials may vary considerably. The base elastomer and the type of vulcanization have a major influence on the principle characteristics of an individual rubber material, as do additives such as fillers, softeners and pigments. These may have a significant effect on the overall properties. The effectiveness, purity, stability and safe handling of a drug preparation may be affected adversely during manufacture, storage and administration if the rubber part used has not been properly selected and validated (approved).

Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 2: Identification and characterization

1 Scope

This part of ISO 8871 specifies evaluation procedures applicable to elastomeric parts used for drug containers and medical devices in order to guarantee the product identity between the samples evaluated in the (suitability test) acceptance process and the current supplies. The physical and chemical test procedures specified in this part of ISO 8871 permit the determination of the typical characteristics of rubber materials, and may serve as a basis for agreements between manufacturer and user regarding the product consistency in subsequent supplies. An appropriate set of tests is selected, depending upon the type of rubber and its application.

This part of ISO 8871 does not specify other requirements for rubber materials. These are laid down in the relevant product standards.

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 48:1994, *Rubber, vulcanized or thermoplastic — Determination of hardness (hardness between 10 IRHD and 100 IRHD)*

ISO 247:1990, *Rubber — Determination of ash*

ISO 2781:1988, *Rubber, vulcanized — Determination of density*

ISO 8871-1:2003, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates*

3 Tests

3.1 General

Rubber is a complex material and not generally definable. The only property which all elastomeric materials have in common is a special type of resilience or elasticity. When a strip of rubber is stretched, it will extend by up to many times its original length without breaking. On release of the stretching force, it snaps back to its original size and shape virtually unaltered. Similarly, one can squeeze it, twist it or distort it in any direction comparatively easily, and it will spring back again to its original shape unchanged.

Owing to its three-dimensional network, achieved by chemical cross-linking of the polymer chains during vulcanization, rubber is practically insoluble in solvents such as tetrahydrofuran, although considerable reversible swelling may occur; this characteristic differentiates rubber from pseudo-elastic materials, such as poly(vinyl chloride) and certain thermoplastic elastomers.

In view of the complexity of rubber, the identity of a given elastomeric material cannot be verified just by applying a single physical or chemical test, and a set of tests is needed for reliable identification.

The manufacturer shall guarantee that all elastomeric parts of current supplies have been produced from the same formulation and that they exhibit the same characteristics as the samples which have been given to the user first and the suitability of which has been proved.

3.2 Hardness

Hardness shall be determined in accordance with ISO 48.

3.3 Density

Density shall be determined in accordance with the procedure described in ISO 2781:1988, method A.

3.4 Ash

The inorganic residue after combustion shall be determined as described in ISO 247:1990, method A.

3.5 Infra-red spectrum

The infra-red spectrum shall be obtained on a pyrolysate as described in Annex A. It shall be compared with a reference spectrum.

3.6 Compression set

The compression set indicates the degree of permanent deformation remaining after compression at a constant deformation and defined temperature for a defined time. The compression set shall be determined in accordance with Annex B.

3.7 Swelling

Elastomeric materials are subject to varying degrees of swelling when exposed to organic solvents; the degree of volume and/or mass increase is primarily influenced by the type of elastomer. Swelling requires special care when the rubber components are in contact with emulsions or oily vehicles.

The relevant procedure is specified in Annex C.

3.8 Development of a fingerprint by gas chromatography

The elastomeric materials under examination are extracted in a solvent, which does not dissolve but might swell the rubber. The extract is injected into a gas chromatograph. The chromatogram obtained exhibits a typical profile and can be used as a fingerprint for identification purposes. Furthermore, GC-coupling techniques, e.g. GC-MS, may provide additional information about the composition of the extract.

The relevant procedure is specified in Annex D.