Irish Standard
I.S. EN ISO 8871-2:2004&A1:2014

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

I.S. EN ISO 8871-2:2004&A1:2014

Incorporating amendments/corrigenda/National Annexes issued since publication:

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8871-2:2004/A1

June 2014

ICS 11.040.20

English Version

Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 2: Identification and characterization - Amendment 1 (ISO 8871-2:2003/Amd 1:2005)

Éléments en élastomère pour administration parentérale et dispositifs à usage pharmaceutique - Partie 2: Identification et caractérisation - Amendement 1 (ISO 8871-2:2003/Amd 1:2005)

Elastomere Teile für Parenteralia und für Geräte zur pharmazeutischen Verwendung - Teil 2: Identifizierung und Charakterisierung (ISO 8871-2:2003/Amd.1:2005)

This amendment A1 modifies the European Standard EN ISO 8871-2:2004; it was approved by CEN on 24 May 2014.

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Foreword

This document (EN ISO 8871-2:2004/A1:2014) 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 Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

This Amendment to the European Standard EN ISO 8871-2:2004 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2014, and conflicting national standards shall be withdrawn at the latest by December 2014.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 8871-2:2003/Amd 1:2005: has been approved by CEN as EN ISO 8871-2:2005/A1:2014 without any modification.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8871-2

September 2004

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Supersedes EN ISO 8871:1997

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.

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Ref. No. EN ISO 8871-2:2004: E

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.

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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
2003-10-01

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

Reference number
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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.

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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.