SLOVENSKI STANDARD
SIST EN ISO 8871-2:2005/A1:2014

01-oktober-2014

Deli iz elastomera za parenteralne farmacevtske oblike - 2. del: Identifikacija in opredelitev - Dopolnilo A1 (ISO 8871-2:2003/Amd 1:2005)

Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 2: Identification and characterization - Amendment 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)

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)

Ta slovenski standard je istoveten z: **EN ISO 8871-2:2004/A1:2014**

ICS:

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

SIST EN ISO 8871-2:2005/A1:2014 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8871-2:2004/A1

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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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This amendment 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 CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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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.

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

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.

INTERNATIONAL STANDARD

ISO 8871-2

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AMENDMENT 1
2005-07-15

Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 2: Identification and characterization

AMENDMENT 1

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

Partie 2: Identification et caractérisation

AMENDEMENT 1

Reference number
ISO 8871-2:2003/Amd.1:2005(E)

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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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Amendment 1 to ISO 8871-2:2003 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This amendment specifies an additional infrared (IR) spectroscopy method coupled with an attenuated total reflection device for the characterization of rubber material by obtaining a fingerprint IR spectrum.

ISO 8871 consist 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*