SLOVENSKI STANDARD
SIST EN ISO 8871-3:2004

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SIST EN ISO 8871:2000
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Elastomeric parts for parenterals and for devices for pharmaceuticals use - Part 3: Determination of released-particle count (ISO 8871-3:2003)

Elastomeric parts for parenterals and for devices for pharmaceuticals use - Part 3: Determination of released-particle count (ISO 8871-3:2003)

Elastomere Teile für Parenteralia und für Geräte zur pharmazeutischen Verwendung - Teil 3: Bestimmung von herausgelösten Partikeln (ISO 8871-3:2003)

Éléments en élastomere pour administration parentérale et dispositifs a usage pharmaceutique - Partie 3: Dénombrement des particules libérées (ISO 8871-3:2003)

Ta slovenski standard je istoveten z: **EN ISO 8871-3:2004**

ICS:

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

SIST EN ISO 8871-3:2004 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8871-3

May 2004

ICS 11.040.20

Supersedes EN ISO 8871:1997

English version

Elastomeric parts for parenterals and for devices for pharmaceuticals use - Part 3: Determination of released-particle count (ISO 8871-3:2003)

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This European Standard was approved by CEN on 1 April 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 Management Centre 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Foreword

The text of ISO 8871-3:2003 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 8871-3:2004 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 November 2004, and conflicting national standards shall be withdrawn at the latest by November 2004.

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 8871-3:2003 has been approved by CEN as EN ISO 8871-3:2004 without any modifications.

INTERNATIONAL STANDARD

ISO 8871-3

First edition
2003-08-01

Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 3: Determination of released-particle count

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

Partie 3: Dénombrement des particules libérées

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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 8871-3 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

When elastomeric closures are used as primary packaging materials in direct contact with pharmaceutical preparations, the pharmaceutical industry requires, to an increasing extent, definite details from the rubber manufacturer about the presence of particles the closures may release into an injectable. The test methods specified in Clauses 3 and 4 make it possible to meet this request.