Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 4: Biological requirements and test methods

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EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 8871-4:2006 sisaldab Euroopa standardi EN ISO 8871-4:2006 ingliskeelset teksti. Käesolev dokument on jõustatud 31.07.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 8871-4:2006 consists of the English text of the European standard EN ISO 8871-4:2006. This document is endorsed on 31.07.2006 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This part of ISO 8871 specifies biological requirements for elastomeric parts for parenterals and for devices for pharmaceutical use. It also specifies the test methods, i.e. it offers the extraction procedures for elastomeric parts, and it makes reference to relevant biological test instructions in Pharmacopoeias and standards.	**Scope:** This part of ISO 8871 specifies biological requirements for elastomeric parts for parenterals and for devices for pharmaceutical use. It also specifies the test methods, i.e. it offers the extraction procedures for elastomeric parts, and it makes reference to relevant biological test instructions in Pharmacopoeias and standards.

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Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 4: Biological requirements and test methods (ISO 8871-4:2006)

Éléments en élastomère pour administration parentérale et dispositifs à usage pharmaceutique - Partie 4: Exigences biologiques et méthodes d'essais (ISO 8871-4:2006)

Elastomere Teile für Parenteralia und für Geräte zur pharmazeutischen Verwendung - Teil 4: Biologische Anforderungen und Prüfverfahren (ISO 8871-4:2006)

This European Standard was approved by CEN on 5 June 2006.

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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Foreword

This document (EN ISO 8871-4:2006) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical and pharmaceutical use" in collaboration with 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 December 2006, and conflicting national standards shall be withdrawn at the latest by December 2006.

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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 8871-4:2006 has been approved by CEN as EN ISO 8871-4:2006 without any modifications.

INTERNATIONAL STANDARD

ISO 8871-4

First edition
2006-06-15

Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 4: Biological requirements and test methods

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

Partie 4: Exigences biologiques 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 8871-4 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This first edition, together with parts 1, 2, 3 and 5, cancels and replaces ISO 8871:1990 and ISO 8871:1990/Amd.1:1995, 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 pharmaceutical industry requires, to an increasing extent, concrete details from the rubber manufacturer about the biological status of rubber closures as far as elastomeric closures are used as primary packaging materials in direct contact with the medicinal products. This request has been taken into account by preparing Annexes A to D of this part of ISO 8871.

Tests presented in this part of ISO 8871 can be taken into account as a guideline if the question of biological safety arises in context with primary packaging materials for pharmaceutical products. The use of certain tests of Annex A to Annex D in case of special applications of the packaging material should be agreed upon between users and manufacturers.

Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 4: Biological requirements and test methods

1 Scope

This part of ISO 8871 specifies biological requirements for elastomeric parts for parenterals and for devices for pharmaceutical use. It also specifies the test methods, i.e. it offers the extraction procedures for elastomeric parts, and it makes reference to relevant biological test instructions in Pharmacopoeias and 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 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

USP, The United States Pharmacopeia, United States Pharmacopeial Convention, Inc., Rockville, MD, USA

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
bacterial endotoxins
lipo-polysaccharides from gram-negative bacteria

3.2
bioburden
population of viable microorganisms on or in product and/or a package

[ISO 11737-1:—, definition 3.1]

3.3
cytotoxicity
biological response of mammalian cell cultures in vitro using appropriate biological parameters to extracts of elastomeric parts

3.4
intracutaneous toxicity
local response to extracts of elastomeric parts after intracutaneous injections into rabbits