Parenteraalsete veel põhinevate ravimpreparaatide jaoks ettenähtud elastomeersed osad

Elastomeric parts for aqueous parenteral preparations

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 8871:1999 sisaldab Euroopa standardi EN ISO 8871:1997+A1:1999 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 8871:1999 consists of the English text of the European standard EN ISO 8871:1997+A1:1999.
Standard on kinnitatud Eesti Standardikeskuse 12.12.1999 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 12.12.1999 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on .	Date of Availability of the European standard text .
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.20

Võtmesõnad: kummitooted, ladu, meditsiiniaparatuur, märgistus, pakkimine, parenteraalse infusiooni seadmestik, tehnilised andmed, testimine,

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8871

July 1997

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Supersedes EN 28871:1993

Descriptors: see ISO document

English version

Elastomeric parts for aqueous parenteral preparations (ISO 8871:1990)

Eléments en élastomère pour préparations aqueuses parentérales (ISO 8871:1990)

Elastomere Teile für wässrige parenterale Zubereitungen (ISO 8871:1990)

This European Standard was approved by CEN on 1997-06-19. 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.

The European Standards exist 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.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart,36 B-1050 Brussels

Ref. No. EN ISO 8871:1997 E

Foreword

The text of the International Standard from Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical use" of the International Organization for Standardization (ISO) has been taken over as an European Standard by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by BSI.

This European Standard replaces EN 28871:1993.

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 January 1998, and conflicting national standards shall be withdrawn at the latest by January 1998.

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

Endorsement notice

The text of the International Standard ISO 8871:1990 has been approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8871:1997/A1

March 1999

ICS 11.040.20

English version

Elastomeric parts for aqueous parenteral preparations (ISO 8871:1997/AM1:1999)

Eléments en élastomère pour préparations aqueuses parentérales (ISO 8871:1997/AM1:1999)

Elastomere Teile für wässrige parenterale Zubereitungen (ISO 8871:1997/AM1:1999)

This amendment A1 modifies the European Standard EN ISO 8871:1997; it was approved by CEN on 19 February 1999.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 8871:1997/A1:1999 E

Foreword

The text of this Amendment EN 8871:1997/A1:1999 to the EN 8871:1997 from Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical use" of the International Organization for Standardization (ISO) has been taken over as an Amendment to the European Standard by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by BSI.

This Amendment to the European Standard EN ISO 8871:1997 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 1999, and conflicting national standards shall be withdrawn at the latest by September 1999.

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

Endorsement notice

The text of the Amendment to the International Standard ISO 8871:1997/Amendment 1:1999 has been approved by CEN as an Amendment to the European Standard without any modification.

NOTE:
This first amendment to the EN ISO 8871: 1997 has two purposes.
One is to incorporate Amendment 1: 1995 to the second edition of ISO 8871: 1990 into the EN ISO 8871: 1997, the text of the amendment being taken over from Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical and pharmaceutical use" of the International Standards Organization (ISO) by Technical Committee CEN/TC 205 "Non-active medical equipment", the secretariat of which is held by BSI. This has been achieved by amending the Foreword and Endorsement notice of EN ISO 8871: 1997.
The other purpose is to add the A-deviation requested by the Swedish member body of CEN, and this has been achieved by adding a new annex ZB.

REVISED TEXT

Foreword
Add a new paragraph as follows:
"Attention is drawn to annex ZB (informative), concerning A-deviations. Annexes N and P form an integral part of this standard."

Endorsement notice
Add a new sentence as follows:
"The text of Amendment 1: 1995 to the International standard ISO 8871: 1990 has been approved by CEN as an amendment to the European Standard without any modification."

Annex ZB
Add a new annex ZB as follows;

"Annex ZB (informative)
A-deviations
A-deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of CEN/CENELEC member:

This European Standard falls under Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

NOTE (from CEN/CENELEC IR Part 2, **3.1.9**): Where standards fall under EC Directives it is the view of the Commission of the European Communities (OJ No G 59, 9.3, 1982) that the effect of the decision of the Court of Justice in case 815/79 Cremonini/Vrankovitch (European Court Reports 1980, p.3583) is that compliance with A-deviations is no longer mandatory and that the free movement of products complying with such a standard should not be restricted except under the safeguard procedure provided for in the relevant Directive.

A-deviations in an EFTA country are valid instead of the relevant provisions of the European Standard in that country until they have been removed.

The European Standard is not in agreement with the European Pharmacopoeia 2nd edition VI.2.3.1, which is mandatory in Sweden, by LVFS 1996:16."

INTERNATIONAL STANDARD

ISO 8871

Second edition
1990-08-01

Elastomeric parts for aqueous parenteral preparations

Éléments en élastomère pour préparations aqueuses parentérales

Reference number
ISO 8871:1990(E)

Contents

International Organization for Standardization
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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.

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.

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

This second edition cancels and replaces the first edition (ISO 8871:1988), presentation has been modified and clauses D.3.2, E.3.2, F.3.2, G.3, J.3.2 and K.3.2 have been technically revised.

Annexes A, B, C, D, E, F, G, H, J, K, L and M form an integral part of this International Standard.

Introduction

The elastomeric parts described in this International Standard are made from a class of material which is generally called "rubber". The parts are made from various elastomers involving different vulcanization systems, and may vary considerably in their composition with regard to fillers, softeners, pigments and other auxiliary ingredients.

The potency, purity, stability, and safety of a drug during its manufacture, storage and administration can be affected by the nature and performance of an elastomeric part used to seal the drug in its final container.

Elastomeric parts for aqueous parenteral preparations

1 Scope

1.1 This International Standard defines procedures for identifying and classifying elastomeric parts for primary packs and medical devices used in direct contact with aqueous preparations for parenteral use including dry preparations which have to be dissolved before use.

This International Standard specifies a series of comparative test methods for chemical and biological evaluation (see clause 6) and describes the various fields of application for elastomeric parts. Dimensions and functional characteristics are specified in the relevant International Standards. Required properties as specified in this International Standard shall be regarded as minimum requirements.

1.2 This International Standard is applicable for the categories of elastomeric parts given in clause 3; specific requirements, however, are laid down in the relevant International Standards dealing with the items or devices listed in clause 3.

NOTE 1 Elastomeric parts for empty syringes for single use are excluded by definition (see ISO 7886).

1.3 Compatibility studies with the intended preparation have to be performed before the approval for final use can be given; however, this International Standard does not specify procedures for carrying out compatibility studies.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 48:1979, *Vulcanized rubbers — Determination of hardness (Hardness between 30 and 85 IRHD).*

ISO 247:1978, *Rubber — Determination of ash.*

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

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods.*

3 Classification

Depending on the intended end-use, elastomeric parts exist in various designs and sizes. These parts serve different purposes depending on the item or device into which they are incorporated; elastomeric parts have, therefore, been classified into the following categories:

— elastomeric parts for injection vials (see ISO 8362-2);

— elastomeric parts for infusion bottles (see ISO 8536-2);

— elastomeric parts for prefilled syringes;

— elastomeric parts for medical devices for pharmaceutical use (excluding gloves and probes);

— elastomeric parts for freeze-dried products.

4 Identification

4.1 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 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,