

Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 2: Identification and characterization

ICS 11.040.20

National foreword

This British Standard is the UK implementation of EN ISO 8871-2:2004+A1:2014. It is identical to ISO 8871-2:2003, incorporating amendment 1:2005. It supersedes BS EN ISO 8871-2:2004, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 29 September 2005

© The British Standards Institution 2014. Published by BSI Standards Limited 2014

ISBN 978 0 580 84962 6

Amendments/corrigenda issued since publication

Date	Comments
31 July 2014	Implementation of ISO amendment 1:2005 with CEN endorsement A1:2014

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.

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.

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 8871-2:2003 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.

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 8871-2:2003 has been approved by CEN as EN ISO 8871-2:2004 without any modifications.

Foreword to amendment A1

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

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
ISO 8871-2:2003(E)
AVA Documents
Document Sharing Hub

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Tests	1
4 Preparation of samples for testing	4
5 Reagents and materials	4
Annex A (informative) Identification of elastomeric material by pyrolysis IR	5
Annex B (informative) Determination of compression set	7
Annex C (informative) Swelling behaviour in oils	9
Annex D (informative) Development of a fingerprint by gas chromatography	11
Annex E (informative) Analysis of volatile components by headspace gas chromatography	13
Annex F (informative) Determination of residual moisture	15
Annex G (informative) Determination of a fingerprint by thermal gravimetry (TG)	16
Annex H (informative) Determination of a fingerprint by surface infrared spectroscopy (ATR, attenuated total reflection)	20
Bibliography	22

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 8871-2 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.