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Elastomere dele til parenterale præparater og udstyr til farmaceutisk brug – Del 2: Identifikation og karakterisering

Elastomeric parts for parenterals and for devices for pharmaceutical use – Part 2: Identification and characterization (ISO 8871-2:2020)

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DS projekt: M331667

ICS: 11.040.20

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IDT med: ISO 8871-2:2020

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EUROPÄISCHE NORM

June 2020

ICS 11.040.20

Supersedes EN ISO 8871-2:2004,
EN ISO 8871-2:2004/A1:2014

English Version

Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 2: Identification and characterization (ISO 8871-2:2020)

Éléments en élastomère pour administration
parentérale et dispositifs à usage
pharmaceutique - Partie 2: identification
et caractérisation (ISO 8871-2:2020)

Elastomere Teile für Parenteralia
und für Geräte zur pharmazeutischen
Verwendung - Teil 2: Identifizierung und
Charakterisierung (ISO 8871-2:2020)

This European Standard was approved by CEN on 21 April 2020.

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

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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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European foreword

This document ([EN ISO 8871-2:2020](#)) 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 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 2020, and conflicting national standards shall be withdrawn at the latest by December 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes [EN ISO 8871-2:2004](#).

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of [ISO 8871-2:2020](#) has been approved by CEN as [EN ISO 8871-2:2020](#) without any modification.

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Second edition
2020-05-14

Elastomere dele til parenterale præparater og udstyr til farmaceutisk brug -

Part 2: Identification and characterization

*Elastomere dele til parenterale præparater og udstyr til farmaceutisk
brug -*

Partie 2: Identification et caractérisation



Reference number
ISO 8871-2:2020(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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition ([ISO 8871-2:2003](http://www.iso.org/iso/8871-2:2003)), which has been technically revised. It also incorporates the Amendment [ISO 8871-2:2003/Amd.1:2005](http://www.iso.org/iso/8871-2:2003/Amd.1:2005). The main changes compared to the previous edition are as follows:

- expansion of the scope to include coated stoppers;
- addition of terms and definitions;
- addition of [H.6](#) on the interpretation of results for ATR.

A list of all parts in the [ISO 8871 series](#) can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

The elastomeric parts specified in the [ISO 8871 series](#) are produced from rubber. However, rubber is not a unique entity, since the composition of rubber materials can 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 might have a significant effect on the overall properties. Polymer coatings or films are often applied to either entire or partial surface(s) of a rubber component to impart certain physical or chemical properties. The effectiveness, purity, stability and safe handling of a drug preparation can be affected adversely during manufacture, storage and administration if the rubber part used has not been properly selected and validated (approved).

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Elastomere dele til parenterale præparater og udstyr til farmaceutisk brug –

Part 2: Identification and characterization (ISO 8871-2:2020)

1 Scope

This document specifies identification and characterization procedures applicable to elastomeric parts including coated stoppers used for drug containers and medical devices.

The physical and chemical test procedures specified in this document permit the determination of the typical characteristics of elastomeric parts including coatings and surface treatments and can serve as a basis for agreements between manufacturer and user regarding the product consistency in subsequent supplies. Depending upon the type of elastomer and its application, an appropriate set of tests is selected.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 48-4](#), *Rubber, vulcanized or thermoplastic — Determination of hardness — Part 4: Indentation hardness by durometer method (Shore hardness)*

[ISO 247-1:2018](#), *Rubber — Determination of ash — Part 1: Combustion method*

[ISO 2781:2018](#), *Rubber, vulcanized or thermoplastic — Determination of density*

[ISO 8871-1](#), *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates*