SLOVENSKI STANDARD
SIST EN ISO 8871-2:2020

01-julij-2020

Nadomešča:
SIST EN ISO 8871-2:2005
SIST EN ISO 8871-2:2005/A1:2014

Deli iz elastomera za parenteralne farmacevtske oblike - 2. del: Identifikacija in opredelitev (ISO 8871-2:2020)

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

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

Ta slovenski standard je istoveten z: **EN ISO 8871-2:2020**

ICS:

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

SIST EN ISO 8871-2:2020 **en**

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 8871-2

June 2020

ICS 11.040.20

Supersedes EN ISO 8871-2:2004

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: dentification 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)

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SIST EN ISO 8871-2:2020

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of an identical text or by endorsement, at the latest by December 2020, and conflicting national standards shall be withdrawn at the latest by December 2020.

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SIST EN ISO 8871-2:2020

INTERNATIONAL STANDARD

ISO 8871-2

Second edition
2020-05

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

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Reference number
ISO 8871-2:2020(E)

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Published in Switzerland

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Foreword

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This second edition cancels and replaces the first edition (ISO 8871-2:2003), which has been technically revised. It also incorporates the Amendment 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.

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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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