
**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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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).

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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), 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.

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.

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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