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Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 5: Functional requirements and testing

*Éléments en élastomère pour administration parentérale et dispositifs à
usage pharmaceutique —*

Partie 5: Exigences fonctionnelles et essais



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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.

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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 8871-5 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This first edition of ISO 8871-5, together with ISO 8871-1, ISO 8871-2, ISO 8871-3 and ISO 8871-4, cancels and replaces ISO 8871:1990 and its Amendment 1:1995, which have 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*

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Introduction

Elastomeric or rubber closures for pharmaceutical use are used in combination with vials and many times in conjunction with piercing devices. There are three functional parameters which are important to the piercing process. These are: penetrability, fragmentation and self-sealing. The three functional tests described in this part of ISO 8871 can be used as a reference method for testing elastomeric closures that are pierced using injection needles made from metal. In addition, the container/closure seal integrity test can be used to verify the effectiveness of the sealing of a specific closure/vial combination.