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## **Transfer sets for pharmaceutical preparations — Requirements and test methods**

*Ensemble de transfert pour préparations pharmaceutiques —  
Exigences et méthodes d'essai*



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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](http://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](http://www.iso.org/patents)).

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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](http://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 third edition cancels and replaces the second edition (ISO 22413:2010), which has been technically revised.

The main changes compared to the previous edition are as follows:

- the structure (moving all tests to the new [Annex A](#)) and partly the content were aligned with ISO 8536-4;
- [Table 1](#) on penetration force was amended by a new entry;
- [6.7](#) (formerly 5.7) on fragmentation was clarified;
- former Clause 12 on storage was deleted;
- [Clause 10](#) (formerly Clause 13) on labelling was updated;
- [Clause 11](#) on the disposal has been added due to the single-use character of the product;
- former Annexes A and B on testing of fragmentation of transfer sets were moved to a new [Annex A](#) on physical tests;
- most of the tests in [Annex A](#) were, as far as necessary, aligned with the appropriate tests in ISO 8536-4;
- a new [Clause A.9](#) on a test for stress cracking of small-bore connectors was added;
- [Clause 2](#) and the Bibliography were updated.

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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](http://www.iso.org/members.html).

## Introduction

Transfer sets for pharmaceutical preparations transmit fluids from one container to another. The transfer sets mix fluids or dissolve dry substances and are used in combination with infusion and injection containers.

The transfer sets consist either of two piercing devices or of a piercing device in combination with a small-bore connector, which can be connected with each other in different ways. Transfer sets can have a housing.

Examples of different designs:

- a) two piercing devices connected to each other (similar to piercing devices of infusion containers);
- b) a metal cannula, bevelled on both sides or a combination of a) and b);
- c) metal cannulae, mostly having a hub or a grip plate in the middle, fixed to the plastic part;
- d) plastic piercing devices directly connected to a grip plate, or held by a tube at a distance to allow a higher hydrostatic pressure;
- e) piercing devices with an additional ventilation channel that can end in the other tip or outside;
- f) piercing devices with an air filter;
- g) piercing device in combination with a small-bore connector;
- h) piercing device in combination with a small-bore connector and a particle filter;
- i) piercing devices with housings serving, among other things, as a guide and a fixation on the connected containers for a secure, injury-free and contactless application.