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

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

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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 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.