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Transfer sets for pharmaceutical preparations — Requirements and test methods

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 08/21

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EUROPEAN STANDARD

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EN ISO 22413

June 2021

ICS 11.040.20 Supersedes EN ISO 22413:2013

English Version

Transfer sets for pharmaceutical preparations - Requirements and test methods (ISO 22413:2021)

Ensemble de transfert pour préparations pharmaceutiques - Exigences et méthodes d'essai (ISO 22413:2021)

Überleitgeräte für pharmazeutische Zubereitungen - Anforderungen und Prüfverfahren (ISO 22413:2021)

This European Standard was approved by CEN on 23 April 2021.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 22413:2021) 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of an identical text or by endorsement, at the latest by December 2021, and conflicting national standards shall be withdrawn at the latest by December 2021.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 22413:2021 has been approved by CEN as EN ISO 22413:2021 without any modification.

INTERNATIONAL STANDARD

ISO 22413

Third edition
2021-06

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).

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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.

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.

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

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.

INTERNATIONAL STANDARD **ISO 22413:2021(E)**

Transfer sets for pharmaceutical preparations — Requirements and test methods

1 Scope

This document specifies requirements and test methods for sterilized single-use transfer sets that are used for pharmaceutical preparations.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7864:2016, *Sterile hypodermic needles for single use — Requirements and test methods*

ISO 8362 (all parts), *— Injection containers and accessories*

ISO 8536 (all parts), *— Infusion equipment for medical use*

ISO 8871-5, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 5: Functional requirements and testing*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 15747, *Plastic containers for intravenous injections*

ISO 15759, *Medical infusion equipment — Plastics caps with inserted elastomeric liner for containers manufactured by the blow-fill-seal (BFS) process*

ISO 80369-1, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-20:2015, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

