



SLOVENSKI STANDARD SIST EN ISO 22413:2021

01-september-2021

Nadomešča:
SIST EN ISO 22413:2013

Pribor za prenos farmacevtskih pripravkov - Zahteve in preskusne metode (ISO 22413:2021)

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

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

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

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Ta slovenski standard je istoveten z: EN ISO 22413:2021

ICS:

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|-----------|-------------------------------------|--|
| 11.120.99 | Drugi standardi v zvezi s farmacijo | Other standards related to pharmaceuticals |
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EUROPEAN STANDARD

EN ISO 22413

NORME EUROPÉENNE

EUROPÄISCHE NORM

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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 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of an identical text or by endorsement, at the latest by December 2021, and conflicting national standards shall be withdrawn at the latest by December 2021.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.

This document supersedes EN ISO 22413:2013.

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

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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).

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).

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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.

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