

Ravimpreparaatide ülekandeseadmed. Nõuded ja katsemeetodid (ISO 22413:2010)

Transfer sets for pharmaceutical preparations - Requirements and test methods (ISO 22413:2010)

EESTI STANDARDI EESSÕNA

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English Version

**Transfer sets for pharmaceutical preparations - Requirements
and test methods (ISO 22413:2010)**

Ensemble de transfert pour préparations pharmaceutiques
- Exigences et méthodes d'essai (ISO 22413:2010)

Überleitgeräte für pharmazeutische Zubereitungen -
Anforderungen und Prüfverfahren (ISO 22413:2010)

This European Standard was approved by CEN on 8 January 2013.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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Foreword

The text of ISO 22413:2010 has been prepared by Technical Committee ISO/TC 76 “Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 22413:2013 by 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of an identical text or by endorsement, at the latest by August 2013, and conflicting national standards shall be withdrawn at the latest by August 2013.

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

This document supersedes EN ISO 22413:2011.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 22413:2010 has been approved by CEN as EN ISO 22413:2013 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on Medical Devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

**Table ZA.1 — Correspondence between this European Standard
and Directive 93/42/EEC on medical devices**

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
5.1, 5.12, 6	7.2	
6, 7	7.3	Presumption of conformity with the Essential Requirements relating to biological evaluation can only be provided if the manufacturer chooses to apply the EN ISO 10993 series of standards, as proposed in the normative reference EN ISO 8536-4.
7	7.5	Presumption of conformity with the Essential Requirements relating to biological evaluation can only be provided if the manufacturer chooses to apply the EN ISO 10993 series of standards, as proposed in the normative reference EN ISO 8536-4.
5.3, 5.5, 5.7	7.6	
5.8, 7	8.1	Presumption of conformity with the Essential Requirements relating to biological evaluation can only be provided if the manufacturer chooses to apply the EN ISO 10993 series of standards, as proposed in the normative reference EN ISO 8536-4.

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
5.9, 11, 12	8.3	
7	8.4	Presumption of conformity with the Essential Requirements relating to biological evaluation can only be provided if the manufacturer chooses to apply the EN ISO 10993 series of standards, as proposed in the normative reference EN ISO 8536-4.
5.2, 5.6, 5.11	9.1	
5.10.2	9.2	
5.2, 5.6	12.7.1	
5.4	12.8.1	
13	13.3	The part of 13.3 a) relating to the authorized representatives is not addressed. ERs 13.3 c) relating to the symbol STERILE and 13.3 f) relating to single-use are not fully addressed.
3.3	13.3 (b)	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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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 Luer connector, which may be connected with each other in different ways. Transfer sets may 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 to be 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 may end in the other tip or outside;
- f) piercing devices also with an air filter;
- g) 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;
- h) piercing device in combination with a Luer connector;
- i) piercing device in combination with a Luer connector and a particle filter.

Transfer sets for pharmaceutical preparations — Requirements and test methods

1 Scope

This International Standard applies to sterilized single use transfer sets that are used for pharmaceutical preparations.

2 Normative references

The following referenced documents are indispensable for the application 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 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 7864:1993, *Sterile hypodermic needles for single use*

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

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

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*

3 Design and designation

3.1 Design

The designs of the individual components are given in Figures 1 to 7. The drawings serve as an illustration of possible transfer sets. Other designs are acceptable.

The Key for Figures 1 to 7 is to be found on page 3.