Irish Standard
I.S. EN ISO 22413:2011

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

I.S. EN ISO 22413:2011

Incorporating amendments/corrigenda/National Annexes issued since publication:

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S.R. xxx: Standard Recommendation - recommendation based on the consensus of an expert panel and subject to public consultation.

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EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 22413

June 2011

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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 5 May 2011.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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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 22413:2011 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 December 2011, and conflicting national standards shall be withdrawn at the latest by December 2011.

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 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(s).

For relationship with EU Directive(s), 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 22413:2010 has been approved by CEN as a EN ISO 22413:2011 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EC 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)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
3.3	13.3 (b)	
4	1, 2, 3	
5.1	7.2	
5.2	9.1, 12.7.1	
5.3	7.6	
5.4	12.8.1	
5.5	7.6	
5.6	9.1, 12.7.1	
5.7	7.6	
5.8	8.1	
5.9	8.3	
5.10.2	9.2	
5.11	9.1	
5.12	7.2	
6	7.1, 7.2, 7.3	
7	7.3, 7.5, 8.1, 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 standard, as proposed in the normative reference EN ISO 8536-4.

Table ZA.1 (continued)

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
11	5, 8.3	
12	5, 8.3	
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.

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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I.S. EN ISO 22413:2011

INTERNATIONAL STANDARD

ISO 22413

Second edition
2010-06-15

Transfer sets for pharmaceutical preparations — Requirements and test methods

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

Reference number
ISO 22413:2010(E)

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 22413 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 22413:2007), of which the scope was enhanced by introducing further product groups like transfer sets with integrated Luer connectors and particle filters. In that framework the following major changes were introduced:

— the Introduction was amended by h) and j);

— the Normative references were updated;

— the Figures in 3.1 were updated;

— 5.11 and 8.10 on the physical requirements and testing for Luer connector were added;

— 5.12 and 8.11 on the physical requirements and testing for filter for particles were added.

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.