SLOVENSKI STANDARD
SIST EN ISO 22413:2013

01-maj-2013

Nadomešča:
SIST EN ISO 22413:2011

Pribor za prenos farmacevtskih pripravkov - Zahteve in preskusne metode (ISO 22413:2010)

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

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

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

Ta slovenski standard je istoveten z: **EN ISO 22413:2013**

ICS:

11.120.99	Drugi standardi v zvezi s farmacijo	Other standards related to pharmaceutics

SIST EN ISO 22413:2013 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 22413

February 2013

ICS 11.040.20

Supersedes EN ISO 22413:2011

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.

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, 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 United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

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.

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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