SLOVENSKI STANDARD
SIST EN ISO 18113-2:2012

01-januar-2012

Nadomešča:
SIST EN ISO 18113-2:2010

Diagnostični preskusni sistemi in vitro - Informacije proizvajalca (označevanje) - 2. del: Diagnostični reagenti in vitro za poklicno uporabo (ISO 18113-2:2009)

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller - Teil 2: In-vitro-diagnostische Reagenzien für den Gebrauch durch Fachpersonal (ISO 18113-2:2009)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 2: Réactifs de diagnostic in vitro à usage professionnel (ISO 18113-2:2009)

Ta slovenski standard je istoveten z: **EN ISO 18113-2:2011**

ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems

SIST EN ISO 18113-2:2012 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 18113-2

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ICS 11.100.10

Supersedes EN ISO 18113-2:2009

English Version

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This European Standard was approved by CEN on 20 September 2011.

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

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Foreword

This document (EN ISO 18113-2:2011) has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" in collaboration with Technical Committee CEN/TC 140 “In vitro diagnostic 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of an identical text or by endorsement, at the latest by April 2012, and conflicting national standards shall be withdrawn at the latest by October 2014.

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 18113-2:2009.

This new edition contains a revised Annex ZA.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 18113-2:2009 has been approved by CEN as EN ISO 18113-2:2011 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of the EU Directive 98/79/EC on "in vitro Diagnostic Medical Devices"

This European Standard has been prepared under a mandate given to CEN by the European Commission to provide a means of conforming to the Essential Requirements of the New Approach Directive 98/79/EC on "*in vitro* Diagnostic Medical Devices".

Once this European Standard is cited in the Official Journal of the European Union under that Directive and has been implemented as 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 European 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 98/79/EC

Clauses of this European Standard	Essential requirements (ERs) of Directive 98/79/EC	Qualifying comments/Notes
7.7	B.3.1	This standard only covers the second sentence of ER B.3.1 namely the labelling requirements.
5, 6, 7	B.8.1	Presumption of conformity with ER B.8.1 also requires compliance with clauses 4.1, 4.2.1 and 4.6 of EN ISO 18113-1.
5.8, 6.8, 7.10	B.8.3	**NOTE 2**
5.1, 6.2	B.8.4 (a)	**NOTE 1**
5.2.1, 5.3, 6.3.1, 6.4	B.8.4 (b)	
5.2.2, 6.3.2	B.8.4 (d)	Full compliance with ER B.8.4 (d) requires the use of EN 980, clause 5.4: symbol (LOT).
5.7, 6.7	B.8.4 (e)	
5.5, 6.5	B.8.4 (g)	
5.6, 6.6	B.8.4 (h)	
5.8, 6.8	B.8.4 (j)	**NOTE 2**
5.4, 7.3	B.8.5	
5.2.2, 6.3.2	B.8.6	
7.1, 7.2, 7.9, 7.10	B.8.7 (a)	Presumption of conformity with ER B.8.7 (a) requires also compliance with EN ISO 18113-1, clause 4.5, as well as an indication of the in vitro use of the device. **NOTE 1, NOTE 3**
7.6	B.8.7 (b)	
7.9	B.8.7 (c)	**NOTE 3**
7.16	B.8.7 (d)	
7.7	B.8.7 (e)	
7.11	B.8.7 (f)	

Clauses of this European Standard	Essential requirements (ERs) of Directive 98/79/EC	Qualifying comments/Notes
7.12	B.8.7 (g)	
7.4, 7.8, 7.16, 7.18	B.8.7 (h)	Full compliance with ER B.8.7 (h) requires, where applicable, an indication of any particular training needed to operate the device.
7.14, 7.15	B.8.7 (i)	
7.18, 7.13	B.8.7 (j)	
7.5, 7.13	B.8.7 (k)	
7.17	B.8.7 (l)	
7.7	B.8.7 (m)	
7.8	B.8.7 (o)	
7.10	B.8.7 (r)	**NOTE 3**
7.10	B.8.7 (s)	**NOTE 3**

NOTE 1 In the European Union, the name and address of the manufacturer's "EC Authorized representative" is required on the outer container label or in the instructions for use, if the legal manufacturer is not located within the European Union.

NOTE 2 Essential requirement B.8.3 of Directive 98/79/EC should be consulted for a comprehensive list of the information required.

NOTE 3 Essential requirement B.8.7 of Directive 98/79/ EC should be consulted for a comprehensive list of the information required.

INTERNATIONAL STANDARD

ISO 18113-2

First edition
2009-12-15

In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) —

Part 2: *In vitro* diagnostic reagents for professional use

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Partie 2: Réactifs de diagnostic in vitro à usage professionnel

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