SLOVENSKI STANDARD
SIST EN ISO 18113-5:2010

01-marec-2010

Nadomešča:
SIST EN 592:2002

Diagnostični preskusni sistemi in vitro - Informacije proizvajalca (označevanje) - 5. del: Diagnostični instrumenti in vitro za samopreskušanje (ISO 18113-5:2009)

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing (ISO 18113-5:2009)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller - Teil 5: Geräte für in-vitro-diagnostische Untersuchungen zur Eigenanwendung (ISO 18113-5:2009)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 5: Instruments de diagnostic in vitro pour auto-tests (ISO 18113-5:2009)

Ta slovenski standard je istoveten z: **EN ISO 18113-5:2009**

ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems

SIST EN ISO 18113-5:2010 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 18113-5

December 2009

ICS 11.100.10

Supersedes EN 592:2002

English Version

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing (ISO 18113-5:2009)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 5: Instruments de diagnostic in vitro pour auto-tests (ISO 18113-5:2009)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller - Teil 5: Geräte für in-vitro-diagnostische Untersuchungen zur Eigenanwendung (ISO 18113-5:2009)

This European Standard was approved by CEN on 18 November 2009.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, 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.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword

This document (EN ISO 18113-5:2009) 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 June 2010, and conflicting national standards shall be withdrawn at the latest by December 2012.

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 592:2002.

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, 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 18113-5:2009 has been approved by CEN as a EN ISO 18113-5:2009 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 confers, within the limits of the scope of this International Standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA — Correspondence between this European Standard and European Directive 98/79/EC

Clause(s)/subclause(s) of this International Standard	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying remarks/Notes
4	B.8.1, B.8.2	
5.1	B.8.2	
5.2.1	B.8.4 (b)	
5.2.2	B.8.4 (d)	
5.2.3	B.8.4 (g)	
6	B.8.1	
7.1	B.8.7 (a)	See Notes 1 and 2
7.2.1	B.8.7 (a)	See Note 2
7.2.2	B.8.7 (e)	
7.3	B.7, B.8.5	
7.4	B.8.7 (a)	See Note 2
7.5	B.8.7 (a), B.8.7 (q), B.8.7(r), B.8.7 (s)	See Note 2
7.6	B.8.7 (m), B.8.7 (n)	
7.7	B.8.7 (h), B.8.7 (t)	
7.8	B.8.7 (d)	

Table ZA (continued)

Clause(s)/subclause(s) of this International Standard	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying remarks/Notes
7.9	B.8.7 (h), B.8.7 (r)	
7.10	B.8.7 (e), B.8.7 (f), B.8.7 (m), B.8.7 (n), B.8.7 (o)	
7.11	B.7, B.8.7 (a), B.8.7 (g), B.8.7 (h)	See Note 2
7.12	B.7.2, B.8.7 (k), B.8.7 (t)	
7.13	B.8.7 (t)	
7.14	B.8.7 (g), B.8.7 (k), B.8.7 (t)	
7.15	B.8.7 (g)	
7.16	B.8.7 (n), B.8.7 (s)	
7.17	B.8.7 (n), B.8.7 (q)	
7.18	B.8.7 (j), B.8.7 (t)	
7.19	B.8.7 (t)	

GENERAL NOTE The presumption of conformity depends on applying all relevant requirements of ISO 18113-1.

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.8.7 of Directive 98/79/EC should be consulted for a comprehensive list of the information required.

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

INTERNATIONAL STANDARD

ISO 18113-5

First edition
2009-12-15

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

Part 5: *In vitro* diagnostic instruments for self-testing

Dispositifs médicaux de diagnostic in vitro — *Informations fournies par le fabricant (étiquetage) —*

Partie 5: Instruments de diagnostic in vitro *pour auto-tests*

Reference number
ISO 18113-5:2009(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page