

# SLOVENSKI STANDARD

## SIST EN ISO 18113-4:2012

01-januar-2012

Nadomešča:

SIST EN ISO 18113-4:2010

---

### Diagnostični preskusni sistemi in vitro - Informacije proizvajalca (označevanje) - 4. del: Diagnostični reagenti in vitro za samopreskušanje (ISO 18113-4:2009)

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing (ISO 18113-4:2009)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller - Teil 4: Reagenzien für in-vitro-diagnostische Untersuchungen zur Eigenanwendung (ISO 18113-4:2009)

[SIST EN ISO 18113-4:2012](#)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 4: Réactifs de diagnostic in vitro pour auto-tests (ISO 18113-4:2009)

**Ta slovenski standard je istoveten z: EN ISO 18113-4:2011**

---

#### **ICS:**

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems
-----------	-----------------------------------------	----------------------------------

**SIST EN ISO 18113-4:2012**

**en**

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN ISO 18113-4:2012](https://standards.iteh.ai/catalog/standards/sist/95be35c3-b07a-4992-bf3c-d7f93df158c3/sist-en-iso-18113-4-2012)

<https://standards.iteh.ai/catalog/standards/sist/95be35c3-b07a-4992-bf3c-d7f93df158c3/sist-en-iso-18113-4-2012>

EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 18113-4**

October 2011

ICS 11.100.10

Supersedes EN ISO 18113-4:2009

English Version

**In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing (ISO 18113-4:2009)**

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 4: Réactifs de diagnostic in vitro pour auto-tests (ISO 18113-4:2009)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller - Teil 4: Reagenzien für in-vitro-diagnostische Untersuchungen zur Eigenanwendung (ISO 18113-4:2009)

This European Standard was approved by CEN on 20 September 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.



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

**Management Centre: Avenue Marnix 17, B-1000 Brussels**

<b>Contents</b>	<b>Page</b>
<b>Foreword</b> .....	<b>3</b>
<b>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”</b> .....	<b>4</b>

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN ISO 18113-4:2012](https://standards.iteh.ai/catalog/standards/sist/95be35c3-b07a-4992-bf3c-d7f93df158c3/sist-en-iso-18113-4-2012)  
<https://standards.iteh.ai/catalog/standards/sist/95be35c3-b07a-4992-bf3c-d7f93df158c3/sist-en-iso-18113-4-2012>

## Foreword

This document (EN ISO 18113-4:2011) 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 18113-4:2009.

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 18113-4:2009 has been approved by CEN as EN ISO 18113-4:2011 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 European Directive 98/79/EC**

Clauses of this European Standard	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying comments/Notes
4.3, 6.1, 7.3, 7.11	B.7	These clauses only cover the second sentence of ER B.7, namely the labelling requirements.
4.2, 4.3, 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, 7.9	B.8.3	<b>NOTE 2</b>
5.1, 6.2	B.8.4(a)	<b>NOTE 1</b>
5.2, 5.3, 6.3.1, 6.4	B.8.4(b)	
5.2.2, 6.3.2	B.8.4(d)	Full compliance to 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)	<b>NOTE 2</b>
5.4	B.8.4(k)	
5.4, 7.3	B.8.5	
5.2.2, 6.3.2	B.8.6	
7.1, 7.2, 7.3, 7.8, 7.9	B.8.7(a)	Presumption of conformity with ER B. 8.7(a) requires also compliance with clause 4.5 of EN ISO 18113-1. <b>NOTE 1, NOTE 3</b>
7.5	B.8.7(b)	
7.8	B.8.7(c)	
7.6	B.8.7(e)	
7.10	B.8.7(f)	
7.11	B.8.7(g)	

Clauses of this European Standard	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying comments/Notes
7.4, 7.7	B.8.7(h)	
7.12	B.8.7(k)	NOTE 3
7.6	B.8.7(m)	
7.9	B.8.7(s)	
7.13, 7.14, 7.15, 7.16, 7.17	B.8.7(t)	

**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.

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 18113-4:2012](https://standards.iteh.ai/catalog/standards/sist/95be35c3-b07a-4992-bf3c-d7f93df158c3/sist-en-iso-18113-4-2012)

<https://standards.iteh.ai/catalog/standards/sist/95be35c3-b07a-4992-bf3c-d7f93df158c3/sist-en-iso-18113-4-2012>

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN ISO 18113-4:2012](https://standards.iteh.ai/catalog/standards/sist/95be35c3-b07a-4992-bf3c-d7f93df158c3/sist-en-iso-18113-4-2012)

<https://standards.iteh.ai/catalog/standards/sist/95be35c3-b07a-4992-bf3c-d7f93df158c3/sist-en-iso-18113-4-2012>



INTERNATIONAL  
STANDARD

ISO  
18113-4

First edition  
2009-12-15

---

---

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

Part 4:

***In vitro* diagnostic reagents for self-  
testing**

iTeh STANDARD PREVIEW

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

*Partie 4: Réactifs de diagnostic in vitro pour auto-tests*

<https://standards.iteh.ai/catalog/standards/sist/95be35c3-b07a-4992-bf3c-d7f93df158c3/sist-en-iso-18113-4-2012>



Reference number  
ISO 18113-4:2009(E)

© ISO 2009

**PDF disclaimer**

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 18113-4:2012](https://standards.iteh.ai/catalog/standards/sist/95be35c3-b07a-4992-bf3c-d7f93df158c3/sist-en-iso-18113-4-2012)

<https://standards.iteh.ai/catalog/standards/sist/95be35c3-b07a-4992-bf3c-d7f93df158c3/sist-en-iso-18113-4-2012>

**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2009

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

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](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

Page

Foreword .....	iv
Introduction.....	v
<b>1 Scope .....</b>	<b>1</b>
<b>2 Normative references .....</b>	<b>1</b>
<b>3 Terms and definitions .....</b>	<b>1</b>
<b>4 General .....</b>	<b>2</b>
<b>4.1 Essential requirements .....</b>	<b>2</b>
<b>4.2 Identification of kit components .....</b>	<b>2</b>
<b>4.3 Presentation of the instructions for use .....</b>	<b>2</b>
<b>5 Content of the outer container label.....</b>	<b>2</b>
<b>5.1 Manufacturer.....</b>	<b>2</b>
<b>5.2 Identification of the IVD reagent .....</b>	<b>2</b>
<b>5.3 Contents .....</b>	<b>3</b>
<b>5.4 Intended use .....</b>	<b>3</b>
<b>5.5 <i>In vitro</i> diagnostic use .....</b>	<b>3</b>
<b>5.6 Storage and handling conditions .....</b>	<b>3</b>
<b>5.7 Expiry date .....</b>	<b>3</b>
<b>5.8 Warnings and precautions .....</b>	<b>4</b>
<b>6 Content of the immediate container label.....</b>	<b>4</b>
<b>6.1 General provisions .....</b>	<b>4</b>
<b>6.2 Manufacturer.....</b>	<b>4</b>
<b>6.3 Identification of the IVD reagent .....</b>	<b>4</b>
<b>6.4 Contents .....</b>	<b>4</b>
<b>6.5 <i>In vitro</i> diagnostic use .....</b>	<b>4</b>
<b>6.6 Storage and handling conditions .....</b>	<b>5</b>
<b>6.7 Expiry date .....</b>	<b>5</b>
<b>6.8 Warnings and precautions .....</b>	<b>5</b>
<b>7 Content of the instructions for use .....</b>	<b>5</b>
<b>7.1 Manufacturer.....</b>	<b>5</b>
<b>7.2 Identification of the IVD reagent .....</b>	<b>5</b>
<b>7.3 Intended use .....</b>	<b>5</b>
<b>7.4 Principles of the examination method .....</b>	<b>6</b>
<b>7.5 Components.....</b>	<b>6</b>
<b>7.6 Additional required equipment .....</b>	<b>6</b>
<b>7.7 Reagent preparation.....</b>	<b>6</b>
<b>7.8 Storage and shelf life after first opening .....</b>	<b>6</b>
<b>7.9 Warnings and precautions .....</b>	<b>6</b>
<b>7.10 Primary sample collection, handling and storage .....</b>	<b>7</b>
<b>7.11 Examination procedure.....</b>	<b>7</b>
<b>7.12 Control procedure .....</b>	<b>7</b>
<b>7.13 Reading of examination results .....</b>	<b>7</b>
<b>7.14 Interpretation of results .....</b>	<b>7</b>
<b>7.15 Performance characteristics .....</b>	<b>7</b>
<b>7.16 Biological reference intervals .....</b>	<b>8</b>
<b>7.17 Limitations of examination procedure .....</b>	<b>8</b>
<b>7.18 Literature references.....</b>	<b>8</b>
<b>Bibliography.....</b>	<b>9</b>