

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)

standards.iteh.ai
SIST EN ISO 18113-5:2010

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 18113-5:2010

<https://standards.iteh.ai/catalog/standards/sist/5e537cc4-c646-4327-b86b-2abe33c6fd3b/sist-en-iso-18113-5-2010>

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..... | 3 |
| 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” | 4 |

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 18113-5:2010](https://standards.iteh.ai/catalog/standards/sist/5e537cc4-c646-4327-b86b-2abe33c6fd3b/sist-en-iso-18113-5-2010)
<https://standards.iteh.ai/catalog/standards/sist/5e537cc4-c646-4327-b86b-2abe33c6fd3b/sist-en-iso-18113-5-2010>

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.

[SIST EN ISO 18113-5:2010](https://standards.iteh.ai/catalog/standards/sist/5e537cc4-c646-4327-b86b-2abe33c6fd7b/sist-en-iso-18113-5-2010)

<https://standards.iteh.ai/catalog/standards/sist/5e537cc4-c646-4327-b86b-2abe33c6fd7b/sist-en-iso-18113-5-2010>

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) | |

SIST EN ISO 18113-5:2010

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 18113-5:2010

<https://standards.iteh.ai/catalog/standards/sist/5e537cc4-c646-4327-b86b-2abe33c6fd3b/sist-en-iso-18113-5-2010>

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**

iTeh STANDARD PREVIEW

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

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

<https://standards.iteh.ai/catalog/standards/sist/5e537cc4-c646-4327-b86b-2abe33c6fd3b/sist-en-iso-18113-5-2010>



Reference number
ISO 18113-5:2009(E)

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 18113-5:2010](https://standards.iteh.ai/catalog/standards/sist/5e537cc4-c646-4327-b86b-2abe33c6fd3b/sist-en-iso-18113-5-2010)

<https://standards.iteh.ai/catalog/standards/sist/5e537cc4-c646-4327-b86b-2abe33c6fd3b/sist-en-iso-18113-5-2010>

**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
Web www.iso.org

Published in Switzerland

Contents

Page

| | |
|---|----|
| Foreword | iv |
| Introduction..... | v |
| 1 Scope | 1 |
| 2 Normative references | 1 |
| 3 Terms and definitions | 2 |
| 4 Essential requirements | 2 |
| 5 Labels and marking | 2 |
| 5.1 General | 2 |
| 5.2 Identification of the IVD instrument..... | 2 |
| 6 Elements of the instructions for use | 3 |
| 7 Content of the instructions for use | 3 |
| 7.1 Manufacturer..... | 3 |
| 7.2 Identification of the IVD instrument..... | 3 |
| 7.3 Intended use | 4 |
| 7.4 Storage and handling | 4 |
| 7.5 Warnings and precautions | 4 |
| 7.6 Instrument installation | 4 |
| 7.7 Principles of measurement | 5 |
| 7.8 Performance of the IVD instrument | 5 |
| 7.9 Limitations of use | 5 |
| 7.10 Preparation prior to operation | 5 |
| 7.11 Operating procedure | 5 |
| 7.12 Control procedure | 6 |
| 7.13 Reading of examination results | 6 |
| 7.14 Special functions | 6 |
| 7.15 Shut-down procedure | 6 |
| 7.16 Disposal information | 6 |
| 7.17 Maintenance | 7 |
| 7.18 Troubleshooting | 7 |
| 7.19 Follow-up action | 7 |
| Bibliography..... | 8 |