SLOVENSKI STANDARD
SIST EN ISO 18113-3:2024

01-september-2024

In vitro diagnostični preskusni sistemi - Informacije proizvajalca (označevanje) - 3. del: Diagnostični instrumenti in vitro za strokovno uporabo (ISO 18113-3:2022)

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2022)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller - Teil 3: Geräte für in-vitro-diagnostische Untersuchungen zum Gebrauch durch Fachpersonal (ISO 18113-3:2022)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 3: Instruments de diagnostic in vitro à usage professionnel (ISO 18113-3:2022)

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Ta slovenski standard je istoveten z: **EN ISO 18113-3:2024**

ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems

SIST EN ISO 18113-3:2024 **en,fr,de**

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SIST EN ISO 18113-3:2024
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SIST EN ISO 18113-3:2024

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 18113-3

June 2024

ICS 11.100.10

Supersedes EN ISO 18113-3:2011

English Version

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2022)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 3: Instruments de diagnostic in vitro à usage professionnel (ISO 18113-3:2022)

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This European Standard was approved by CEN on 2 October 2022.

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.

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iTeh Standards
(https://standards.iteh.ai)
Document Preview
SIST EN ISO 18113-3:2024
https://standards.iteh.ai/catalog/standards/sist/e4fd34eb-37c0-4b37-bfc8-5df5fc41fe5d/sist-en-iso-18113-3-2024

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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SIST EN ISO 18113-3:2024

Contents

Page

iTeh Standards
(https://standards.iteh.ai)
Document Preview

SIST EN ISO 18113-3:2024
https://standards.iteh.ai/catalog/standards/sist/e4fd34eb-37c0-4b37-bfc8-5df5fc41fe5d/sist-en-iso-18113-3-2024

SIST EN ISO 18113-3:2024

European foreword

This document (EN ISO 18113-3:2024) has been prepared by Technical Committee ISO/TC 212 "Medical laboratories and in vitro diagnostic 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 December 2024, and conflicting national standards shall be withdrawn at the latest by June 2027.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 18113-3:2011.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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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, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

SIST EN ISO 18113-3:2024
https://standards.iteh.ai/catalog/standards/sist/e4fd34eb-37c0-4b37-bfc8-5df5fc41fe5d/sist-en-iso-18113-3-2024

Endorsement notice

The text of ISO 18113-3:2022 has been approved by CEN as EN ISO 18113-3:2024 without any modification.

SIST EN ISO 18113-3:2024

Annex ZA
(informative)

Relationship between this European Standard the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/746 of 5 April 2017 concerning in vitro diagnostic medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, performance studies, clinical evidence or post-market performance follow-up

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 and application of the edition of the normatively referenced standards as given in Table ZA.2 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/746, the definitions set out in this Regulation prevail.

This document needs to be considered together with the other parts of EN ISO 18113-series to fully apply the concepts of this labelling standard series. EN ISO 18113-1 provides definitions and overall concepts which may be further applied or directed to specific device format and labelling location.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the In vitro Diagnostic Regulation (EU) 2017/746).

Where the standard includes notes that require alignment to local or regional regulations, all clauses need to be read in the context of Regulation (EU) 2017/746.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/746. This means that risks have to be ‘reduced as far as possible’, ‘reduced to a level as low as reasonably practicable’, ‘reduced to the lowest possible level’, ‘reduced as far as possible and appropriate’, ‘removed or reduced as far as possible’, ‘eliminated or reduced as far as possible’, ‘prevented’ or ‘minimized’, according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer’s policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 10, 11, 13, 15, 16, 17, 18 and 19 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

iTeh Standards
(https://standards.iteh.ai)
Document Preview
SIST EN ISO 18113-3:2024

SIST EN ISO 18113-3:2024

Table ZA.1 — Correspondence between this European Standard and Annex I of Regulation (EU) 2017/746 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
4c	7.5	Covered with respect to warnings and precautions to the user when used within a risk management process
7	7.4	Covered with respect to the information provided regarding storage and handling
20.1 g)	7.5 a)	Covered with respect to residual risks related to installation, operation, maintenance, transportation, storage or disposal
20.4.1 a)	7.2.1	Covered
20.4.1 b)	7.2.1	Covered with respect to additional means of identification
20.4.1 f)	7.7	Covered with respect to the basic test principle of the instrument
20.4.1 k)	7.4	Covered
20.4.1 n) i)	7.5	Covered with respect to information for safety
20.4.1 n) ii)	7.5	Covered with respect to information for safety
20.4.1 n) iii)	7.5	Covered with respect to information for safety
20.4.1 t)	7.12	Covered
20.4.1 y)	7.13	Covered
20.4.1 ab)	7.4, 7.9, 7.18 b)	Covered with respect to interfering substances or limitations
20.4.1 ae)	7.20	Covered with respect to document and change control

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SIST EN ISO 18113-3:2024
https://standards.iteh.ai/catalog/standards/sist/e4fd34eb-37c0-4b37-bfc8-3df5fc411e3d/sist-en-iso-18113-3-2024

SIST EN ISO 18113-3:2024

Table ZA.2 — Applicable Standards to confer presumption of conformity as described in this Annex ZA

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO 14971	ISO 14971:2019	Medical devices — Application of risk management to medical devices	EN ISO 14971:2019 EN ISO 14971:2019/A11:2021
ISO 15223-1	ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	EN ISO 15223-1:2021
ISO 18113-1	ISO 18113-1:2022	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions, and general requirements	EN ISO 18113-1:2024
IEC 61010-1	IEC 61010-1:2010 IEC 61010-1:2010/A1:2016 IEC 61010-1:2010/A1:2016/COR1:2019	Safety requirements for electrical equipment for measurement, control and laboratory use — Part 1: General requirements	EN 61010-1:2010 EN 61010-1:2010/A1:2019 EN 61010-1:2010/A1:2019/AC:2019
IEC 61010-2-101	IEC 61010-2-101:2018	Safety requirements for electrical equipment for measurement, control and laboratory use — Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment	EN IEC 61010-2-101:2022 EN IEC 61010-2-101:2022/A11:2022
IEC 61326-2-6	IEC 61326-2-6:2020	Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 2-6: Particular requirements — In vitro diagnostic (IVD) medical equipment	EN IEC 61326-2-6:2021
IEC 62366-1	IEC 62366-1:2015 IEC 62366-1:2015/Cor 1:2016 IEC 62366-1:2015/A1:2020	Medical devices — Application of usability engineering to medical devices	EN 62366-1:2015 EN 62366-1:2015/AC:2015 EN 62366-1:2015/A1:2020

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SIST EN ISO 18113-3:2024
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SIST EN ISO 18113-3:2024

The documents listed in the Column 1 of Table ZA.2, in whole or in part, are normatively referenced in this document and are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of Table ZA.2.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

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SIST EN ISO 18113-3:2024
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SIST EN ISO 18113-3:2024

INTERNATIONAL STANDARD

ISO 18113-3

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

Part 3: In vitro diagnostic instruments for professional use

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

Partie 3: Instruments de diagnostic in vitro à usage professionnel

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Document Preview

SIST EN ISO 18113-3:2024
https://standards.iteh.ai/catalog/standards/sist/e4fd34eb-37c0-4b37-bfc8-5df5fc41fe5d/sist-en-iso-18113-3-2024

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