SLOVENSKI STANDARD
SIST EN ISO 20916:2024

01-maj-2024

Diagnostični medicinski pripomočki in vitro - Klinične študije učinkovitosti z uporabo človeških vzorcev - Dobre študijske prakse (ISO 20916:2019)

In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019)

In-vitro-Diagnostika - Klinische Leistungsuntersuchungen an menschlichem Untersuchungsmaterial - Gute Studienpraxis (ISO 20916:2019)

Dispositifs médicaux de diagnostic in vitro - Études des performances cliniques utilisant des prélèvements de sujets humains - Bonnes pratiques d'étude (ISO 20916:2019)

Ta slovenski standard je istoveten z: **EN ISO 20916:2024**

ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems

SIST EN ISO 20916:2024 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 20916

March 2024

ICS 11.100.10

English Version

In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019)

Dispositifs médicaux de diagnostic in vitro - Études des performances cliniques utilisant des prélèvements de sujets humains - Bonnes pratiques d'étude (ISO 20916:2019)

In-vitro-Diagnostika - Klinische Leistungsuntersuchungen an menschlichem Untersuchungsmaterial - Gute Studienpraxis (ISO 20916:2019)

This European Standard was approved by CEN on 7 August 2023.

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

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

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

Contents

Page

European foreword

The text of ISO 20916:2019 has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 20916:2024 by 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 September 2024, and conflicting national standards shall be withdrawn at the latest by March 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 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. A complete listing of these bodies can be found on the CEN website.

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.

Endorsement notice

The text of ISO 20916:2019 has been approved by CEN as EN ISO 20916:2024 without any modification.

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 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.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/746, the differences shall be indicated in the Annex ZA. 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.

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.

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.

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
3 (b)	C.5	Covered with respect to *in vitro* diagnostic medical devices under clinical performance study
3 (c)	C.5	Covered for *in vitro* diagnostics medical devices under clinical performance study with the exemption of the estimation and evaluation of risks associated with and during the “reasonably foreseeable misuse”
4 (c)	C.5	Covered with respect to safety principles and risk control measures for devices under clinical performance study except aspects regarding training to users.
8	B.7	Covered with respect to the benefit-risk evaluation performed during a clinical performance study
9.1 (a)	5.3 (i)	Covered with respect to the items listed in 5.3 (i) that are included in the clinical performance study.
9.1 (b)	5.3	Covered with respect to the items listed in 5.3 (j) that are included in the clinical performance study. Expected values in normal and affected populations are not covered.
9.4. (a)	5.3 c) 4), 5. 3 g), 5. 3 h)	Covered with respect to the items listed in 5.3 c) 4), 5. 3 g), 5. 3 h) that are included in the clinical performance study.
9.4. (b)	5.3 c) 4), 5. 3 g), 5. 3 h)	Covered with respect to the items listed in 5.3 c) 4), 5. 3 g), 5. 3 h) that are included in the clinical performance study.
20.2 (e)	5.12	Covered with respect to the labelling of the *in vitro* diagnostics medical device under clinical performance study.

Table ZA.2 – Correspondence between this European standard and Annex XIII of Regulation (EU) 2017/746 [OJ L 117]

Requirements of Regulation 2017/746, Annex XIII (EU)	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
2.2	4.1, 4.3, 4.4, 5.5.2 (b), 5.5.2 (n), 5.5.3.17, 5.10 (c), 7.3.1	Covered with respect to ethical considerations
2.3.1	5.3, B.8.1 c)	Covered with respect to the study design, the items listed in 5.3 that are included in the clinical performance study and with respect to bias minimalization
2.3.2 first and second paragraphs	5.5.3	Covered with respect to the content of CPSP
2.3.2 (b)	5.5.3.4	Covered with respect to the sponsor information
2.3.2 (c)	5.9	Covered with respect to study site identification and qualification if included in the clinical performance study
2.3.2 (e)	5.5.3.3, 5.5.3.8	Covered with respect to the information of the *in vitro* diagnostics medical device
2.3.2 (f)	5.5.3.9, 5.7	Covered with respect to the specimen information
2.3.2 (g)	5.5.3.6	Covered with respect to the summary of the study; current state of the art in diagnosis and/or medicine is not covered.
2.3.2 (o)	5.10	Covered
2.3.3	8.2, Annex D	Covered

Table ZA.3 – Correspondence between this European standard and Annex XIV of Regulation (EU) 2017/746 [OJ L 117]

Requirements of Regulation (EU) 2017/746, Annex XIV	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1.6.	5.3, 5.5.3, Annex B	Covered with respect to the design of the clinical performance study and the content of the CPSP
1.10.	5.5.3.3	Covered except the classification of the *in vitro* diagnostics medical device
1.11.	5.5.3.6	Covered
1.12.	5.5.3.8	Covered

Requirements of Regulation (EU) 2017/746, Annex XIV	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1.13.	5.1 3rd paragraph, 6.3	Covered with respect to qualification evidence of the investigator and the study site
1.13.	5.9	Covered with respect to the capability/suitability of the site
1.17.	Annex C.6	Covered with respect to the list of applied standards
2.	Annex C	Covered with respect to IB
2.5.	Annex B.7 and C.5	Covered
2.7.	Annex C.6 a) and b)	Covered with respect to the list of applied standards
3.	5.5.3	Covered with respect to the content of the CPSP
4.2.	6.2 f), Annex E.3	Covered
4.4.	4.5, Annex A.8 2nd paragraphe, Annex E.2 c), Annex F.2, Annex F.4, Annex E.3	Covered with respect to leftover or archived specimen, compensation, needed translation of the document, process for obtaining informed consent and the provided information and content of the informed consent document
4.6.	5.2	Covered with respect to Risk analysis
Chapter II 1.	7.2 c), 7.2. g)	Covered with respect to sponsors obligations to provide information to the authorities
Chapter II 2.	Annex G	Covered with respect to the categorisation of adverse events
Chapter II 4.	5.10	Covered with respect to the study monitoring obligations, but not with respect to the independence of the monitor

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.

INTERNATIONAL STANDARD

ISO 20916

First edition
2019-05

In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice

Dispositifs médicaux de diagnostic in vitro — Études des performances cliniques utilisant des prélèvements de sujets humains — Bonnes pratiques d'étude

Reference number
ISO 20916:2019(E)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

