SLOVENSKI STANDARD
oSIST prEN ISO 20916:2021

01-september-2021

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: **prEN ISO 20916**

ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems

oSIST prEN ISO 20916:2021 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN ISO 20916

April 2021

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 draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 140.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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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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 prEN ISO 20916:2021 by Technical Committee CEN/TC 140 "In vitro diagnostic medical devices" the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

This document has been prepared under a standardization request given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Regulation(s).

For relationship with EU Regulation(s), see informative Annex ZA, which is an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard "within the meaning of Annex ZA", the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these references documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlations between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO or IEC
Not applicable	Not applicable	Not applicable

Endorsement notice

The text of ISO 20916:2019 has been approved by CEN as prEN ISO 20916:2021 without any modification.

Annex ZA
(informative)

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

This European standard has been prepared under a Commission's standardisation request [Full reference to the request "M/xxx"] 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].

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.

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 This Annex ZA is based on normative references according to the table of references in the European Foreword, replacing the references in the core text.

NOTE 4 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]

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
2	5.2, B.7	Covered with respect to the benefit-risk evaluation performed during a clinical performance study
3 (a)	C.5	Covered with respect to medical devices under clinical investigation
3 (b)	C.5	Covered with respect to medical devices under clinical investigation
3 (c)	C.5	Covered with respect to medical devices under clinical investigation

3 (d)	C.5	Covered with respect to medical devices under clinical investigation
3 (e)	C.5	Covered with respect to medical devices under clinical investigation during post market surveillance
4 (c)	C.5	Covered with respect to safety principles and risk control measures for devices under clinical investigation
5 (a)	C.5	Covered with respect to medical devices under clinical investigation
5 (b)	C.5	Covered with respect to medical devices under clinical investigation
6	C.5, D.7.1	Covered with respect to medical devices under clinical investigation, especially for companion diagnostics
8	C.5	Covered with respect to the benefit-risk evaluation performed during a clinical performance study
9.1 (b)	5. 3	Covered
9.4.	5. 3 h), B.8.1 b), C.2 d)	Covered with respect to clinical performance studies
9.4. (a)	5. 3 g), 5. 3 h)	Covered with respect to clinical performance studies
9.4. (b)	5. 3 g), 5. 3 h)	Covered with respect to clinical performance studies
20.2 (e)	5. 12	Covered with respect to the labelling of the device under clinical performance study.
20. 3 (e)	5. 12	Covered regarding devices for clinical performance study
20.4.1 (aa)	5.3 c) 2nd bullet point, 5.3 j)	Covered with respect to characteristics obtained during clinical performance studies

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	Covered with respect to the study design
2.3.1	5.3 o), B.8.1 c)	Covered with respect to bias minimalization

Requirements of Regulation 2017/746, Annex XIII (EU)	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
2.3.2	5.5.3	Covered with respect to the content of CPSP
2.3.2 (a)	5.5.3.2	Covered with respect to the identification of study
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
2.3.2 (e)	5.5.3.3, 5.5.3.8	Covered with respect to the information of the 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
2.3.2 (h)	5.2	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
Chapter I (1st para)	5.2	Covered with respect to risk evaluation
Chapter I (1st para)	Annex F.4 c) 3rd bullet point	Covered with respect to information provided to the subject on the risks associated with the interventional clinical performance study
1.6.	5.3	Covered with respect to the design of the clinical performance study
1.6.	5.5.3, Annex B	Covered with respect to the content of the CPSP
1.10.	5.5.3.3	Covered
1.11.	5.5.3.6	Covered
1.12.	5.5.3.8	Covered
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 and applied essential requirements
2.	Annex C	Covered with respect to IB
2.5.	Annex C.5	Covered
2.7.	Annex C.6 a) and b)	Covered with respect to the list of applied standards and applied essential requirements

Requirements of Regulation (EU) 2017/746, Annex XIV	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
3.	5.5.3	Covered with respect to the content of the CPSP
4.1.	Annex C.6 a) and b)	Covered with respect to the list of applied standards and applied essential requirements
4.2.	6.2 f), Annex E.3	Covered
4.4.	4.5	Covered with respect to leftover or archived specimen
4.4.	Annex A.8 2nd paragraph	Covered with respect to compensation
4.4.	Annex E.2 c)	Covered with respect to needed translation of the document
4.4.	Annex F.2	Covered with respect to the process for obtaining informed consent and the provided information
4.4.	Annex F.4, Annex E.3	Covered with respect to content of the informed consent document
4.5.	7.4	Covered
4.6.	5.2	Covered with respect to Risk analysis
Chapter II 1.	7.2 c)	Covered with respect to sponsors obligations to provide information to the authorities
Chapter II 1.	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 3.	8.3	Covered
Chapter II 4.	5.10	Covered with respect to the study monitoring obligations

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

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.