SLOVENSKI STANDARD
SIST EN ISO 14971:2020/A11:2022

01-februar-2022

Medicinski pripomočki - Uporaba obvladovanja tveganja pri medicinskih pripomočkih (ISO 14971:2019) - Dopolnilo A11

Medical devices - Application of risk management to medical devices (ISO 14971:2019)

Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte (ISO 14971:2019)

Dispositifs médicaux - Application de la gestion des risques aux dispositifs médicaux (ISO 14971:2019)

Ta slovenski standard je istoveten z: EN ISO 14971:2019/A11:2021

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN ISO 14971:2020/A11:2022 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14971:2019/A11

December 2021

ICS 11.040.01

English version

Medical devices - Application of risk management to medical devices (ISO 14971:2019)

Dispositifs médicaux - Application de la gestion des risques aux dispositifs médicaux (ISO 14971:2019)

Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte (ISO 14971:2019)

This amendment A11 modifies the European Standard EN ISO 14971:2019; it was approved by CEN on 27 October 2021.

CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 and CENELEC member.

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees 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, Turkey and United Kingdom.

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

Ref. No. EN ISO 14971:2019/A11:2021 E

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European foreword

This document (EN ISO 14971:2019/A11:2021) has been prepared by Technical Committee CEN/CLC/TC 3 “Quality management and corresponding general aspects for medical devices” the secretariat of which is held by NEN.

This Amendment to the European Standard EN ISO 14971:2019 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2022, and conflicting national standards shall be withdrawn at the latest by June 2022.

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 Amendment to the European Standard EN ISO 14971:2019 has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports requirements of EU Regulation(s).

For relationship with EU Regulation(s), see informative Annex ZA, and ZB, which are 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 websites.

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, Turkey and the United Kingdom.

Annex ZA
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under a Commission's standardisation request M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning 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.

For application of this European standard under Regulation (EU) 2017/745,

1. the scope is limited to medical devices and accessories for a medical device as defined in that Regulation and to products regulated as a device under that Regulation;

2. in case of differences between terms defined in this European standard and terms defined in that Regulation, the terms defined in the Regulation shall prevail;

3. the manufacturer's policy for establishing criteria for risk acceptability (see 4.2 of this European standard) shall ensure that the criteria comply with the General Safety and Performance Requirements of that Regulation.

Explanation on the correspondence of the standard and the General Safety and Performance Requirements is included in Table ZA.1.

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) 2017/745. This means that risks have to be 'reduced as far as possible', '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', 'removed or minimized as far as possible', 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, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 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) 2017/745 [OJ L 117]

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / subclause(s) of this EN	Remarks / Notes
3, first paragraph	4.1 to 4.5	Covered.
3, second paragraph	4.1, 4.2	Covered.
3, item (a)	4.4	Covered in respect of the process requirements.
3, item (b)	5	Covered in respect of the process requirements. Device-specific execution of the process is not covered.
3, item (c)	5.5, 6	Covered in respect of the process requirements. Device-specific execution of the process is not covered.
3, item (d)	7	Covered in respect of the process requirements. Device-specific execution of the process is not covered.
3, item (e)	10	Covered in respect of the process requirements. Device-specific execution of the process is not covered.
3, item (f)	10.4	Covered in respect of the process requirements. Device-specific execution of the process is not covered.
4, first paragraph	4.2, 4.4, 6, 7, 8	Covered in respect of the process requirements. Device-specific execution of the process is not covered.
4, item (a)	7.1 a)	Covered in respect of the process requirements. Device-specific execution of the process is not covered.
4, item (b)	7.1 b)	Covered in respect of the process requirements. Device-specific execution of the process is not covered.

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / subclause(s) of this EN	Remarks / Notes
4, item (c)	7.1 c)	Covered in respect of the process requirements. Device-specific execution of the process is not covered.
4, last paragraph	8 (second paragraph)	Covered.
5, item (a)	5.2, 5.3, 5.4, 7	Covered in respect of the process requirements. Device-specific and usability-specific execution of the process is not covered.
5, item (b)	5.2, 5.3, 5.4	Covered in respect of the process requirements. Device-specific and usability-specific execution of the process is not covered.
8	6, 7, 8	Covered in respect of the process requirements. Device-specific execution of the process is not covered.
9	1 to 10	Covered, provided that the criteria for risk acceptability are established in accordance with GSPR 9.

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.

Annex ZB
(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 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].

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 ZB.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.

For application of this European standard under Regulation (EU) 2017/746,

1. the scope is limited to *in vitro* diagnostic medical devices and accessories for *in vitro* diagnostic medical devices as defined in that Regulation and to products regulated as a device under that Regulation;

2. in case of differences between terms defined in this European standard and terms defined in that Regulation, the terms defined in the Regulation shall prevail;

3. the manufacturer's policy for establishing criteria for risk acceptability (see 4.2 of this European standard) shall ensure that the criteria comply with the General Safety and Performance Requirements of that Regulation.

Explanation on the correspondence of the standard and the General Safety and Performance Requirements is included in Table ZB.1.

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 ZB 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 ZB.1, it means that it is not addressed by this European Standard.

Table ZB.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) / subclause(s) of this EN	Remarks / Notes
3, first paragraph	4.1 to 4.5	Covered.
3, second paragraph	4.1, 4.2	Covered.
3, item (a)	4.4	Covered in respect of the process requirements.
3, item (b)	5	Covered in respect of the process requirements. Device-specific execution of the process is not covered.
3, item (c)	5.5, 6	Covered in respect of the process requirements. Device-specific execution of the process is not covered.
3, item (d)	7	Covered in respect of the process requirements. Device-specific execution of the process is not covered.
3, item (e)	10	Covered in respect of the process requirements. Device-specific execution of the process is not covered.
3, item (f)	10.4	Covered in respect of the process requirements. Device-specific execution of the process is not covered.
4, first paragraph	4.2, 4.4, 6, 7, 8	Covered in respect of the process requirements. Device-specific execution of the process is not covered.
4, item (a)	7.1 a)	Covered in respect of the process requirements. Device-specific execution of the process is not covered.
4, item (b)	7.1 b)	Covered in respect of the process requirements. Device-specific execution of the process is not covered.