SLOVENSKI STANDARD
SIST EN ISO 14971:2012

01-september-2012

Nadomešča:
SIST EN ISO 14971:2009

Medicinski pripomočki - Uporaba obvladovanja tveganja pri medicinskih pripomočkih (ISO 14971:2007, popravljena verzija 2007-10-01)

Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)

Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte (ISO 14971:2007, korrigierte Fassung 2007-10-01)

Dispositifs médicaux - Application de la gestion des risques aux dispositifs médicaux (ISO 14971:2007, Version corrigée de 2007-10-01)

Ta slovenski standard je istoveten z: **EN ISO 14971:2012**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN ISO 14971:2012 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 14971

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ICS 11.040.01

Supersedes EN ISO 14971:2009

English version

Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)

Dispositifs médicaux - Application de la gestion des risques aux dispositifs médicaux (ISO 14971:2007, Version corrigée de 2007-10-01)

Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte (ISO 14971:2007, korrigierte Fassung 2007-10-01)

This European Standard was approved by CEN on 16 May 2012.

CEN and CENELEC 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 and CENELEC 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 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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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Foreword

The text of ISO 14971:2007, Corrected version 2007-10-01, has been prepared by Technical Committee ISO/TC 210 “Quality management and corresponding general aspects for medical devices” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 14971:2012 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 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 January 2013, and conflicting national standards shall be withdrawn at the latest by January 2013.

This document supersedes EN ISO 14971:2009.

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 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 Directives 93/42/EEC on Medical Devices, 90/385/EEC on Active Implantable Medical Devices and 98/79/EC on In Vitro Diagnostic Devices.

For relationship with EU Directives, see informative Annexes ZA, ZB and ZC, which are an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 14971:2007, Corrected version 2007-10-01, has been approved by CEN as an EN ISO 14971:2012 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and Requirements of EU Directive 93/42/EEC on Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Requirements of the New Approach Directive 93/42/EEC on Medical Devices.

Within the limits of the scope of this standard (Clause 1 of EN ISO 14971:2012), compliance with the clauses of this standard confers a presumption of conformity with requirements of that Directive and associated EFTA regulations, once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State. This Annex ZA explains to which requirements, under which conditions and to what extent presumption of conformity can be claimed.

Whilst only a limited number of requirements is covered just by the application of this standard, authorities in charge of medical devices strongly recommend using this standard. The standard leads, according to experience of the authorities, to a higher degree of compliance with legal obligations.

EN ISO 14971:2012 provides a process for managing risks associated with medical devices. Because this standard describes an ongoing, lifecycle process applicable in part or in all to the Essential Requirements of Directive 93/42/EEC on Medical Devices, it is – very exceptionally – not meaningful to link individual clauses of the standard to specific corresponding Essential Requirements.

Compliance with all the normative clauses in EN ISO 14971 will ensure that a process is in place to address general risk management aspects related to medical devices, which are included in the Essential Requirements. However, because this is an international standard, intended to be applicable in jurisdictions all over the world, it is not the primary goal of the standard to cover exactly any of the European Essential Requirements. Therefore, for all of the Essential Requirements, conformity is not entirely achieved by complying only with the requirements specified in this standard. Manufacturers and conformity assessment bodies will need to feed the Essential Requirements into the risk management process provided by the standard. Explanation on the correspondence of the standard and the Essential Requirements is included in Table ZA.1. Further explanation on content deviations between the standard and the ERs is provided below the table.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
1-9	1	ER 1 is not directly covered by EN ISO 14971, since the standard does not provide requirements on design and manufacture. However, the standard provides a tool to generate the information that is a necessary preliminary step for a manufacturer to demonstrate that the device is in conformity with ER 1. For content deviations, see points 1, 2, 3, 4 below.
1-9	2	- The second sentence of ER 2 is partly covered by 6.2. For content deviations, see points 1, 2, 3, 5, 6, 7 below. - The other parts of ER 2 are not directly covered by EN ISO 14971, since the standard does not provide requirements on design and construction, nor does it apply the concept of 'safety principles' as intended in the MDD. However, the standard provides a tool to generate the information that is a necessary preliminary step for a manufacturer to demonstrate that the device is in conformity with ER 2.
1-9	4	ER 4 is not directly covered by EN ISO 14971, since the standard does not apply the concept of 'safety principles' as intended in the MDD. However, the standard provides a tool to generate the information that is a necessary preliminary step for a manufacturer to demonstrate that the device is in conformity with ER 4.
1-9	5	ER 5 is not directly covered by EN ISO 14971, since the standard does not provide requirements on design, manufacture or packaging. However, the standard provides a tool to generate the information that is a necessary preliminary step for a manufacturer to demonstrate that the device is in conformity with ER 5.

6.4, 6.5 and 7	6	ER 6 is covered. However, for content deviations, see points 1, 2, 3, 4 below.
1-9	7.1	ER 7.1 is only partly covered by EN ISO 14971, since the standard does not provide requirements on design and manufacture and does not cover performances and characteristics related thereto. Furthermore, it does not provide specific requirements on the items that must be paid particular attention. However, the standard provides a tool to generate the information that is a necessary preliminary step for a manufacturer to demonstrate that the device is in conformity with ER 7.1. For content deviations, see points 1 to 7 below.

Content deviations

The following aspects have been identified where the standard deviates or might be understood as deviating from the Essential Requirements:

1. Treatment of negligible risks:

a) According to standard ISO 14971, the manufacturer may discard negligible risks[1].
b) However, Sections 1 and 2 of Annex I to Directive 93/42/EEC require that all risks, regardless of their dimension, need to be reduced as much as possible and need to be balanced, together with all other risks, against the benefit of the device.
c) Accordingly, the manufacturer must take all risks into account when assessing Sections 1 and 2 of Annex I to Directive 93/42/EEC.

2. Discretionary power of manufacturers as to the acceptability of risks:

a) ISO 14971 seems to imply that manufacturers have the freedom to decide upon the threshold for risk acceptability[2] and that only non-acceptable risks have to be integrated into the overall risk-benefit analysis[3].
b) However, Sections 1 and 2 of Annex I to Directive 93/42/EEC require that all risks have to be reduced as far as possible and that all risks combined, regardless of any "acceptability" assessment, need to be balanced, together with all other risks, against the benefit of the device.
c) Accordingly, the manufacturer may not apply any criteria of risk acceptability prior to applying Sections 1 and 2 of Annex I to Directive 93/42/EEC.

[1] This is explicitly stated in D.8.2.

[2] Sections 5, 6.4, 6.5, 7: reference to the criteria set-up in the management plan which is under the discretion of the manufacturer (see Sections 3.2, 3.4d)). See also D.4: "This International Standard does not specify acceptable risk. That decision is left to the manufacturer."

[3] See D.6.1.

3. Risk reduction "as far as possible" versus "as low as reasonably practicable":

a) Annex D.8 to ISO 14971, referred to in 3.4, contains the concept of reducing risks "as low as reasonably practicable" (ALARP concept). The ALARP concept contains an element of economic consideration.
b) However, the first indent of Section 2 of Annex I to Directive 93/42/EEC and various particular Essential Requirements require risks to be reduced "as far as possible" without there being room for economic considerations.
c) Accordingly, manufacturers and Notified Bodies may not apply the ALARP concept with regard to economic considerations.

4. Discretion as to whether a risk-benefit analysis needs to take place:

a) 6.5 of ISO 14971 says: "If the residual risk is not judged acceptable using the criteria established in the risk management plan and further risk control is not practicable, the manufacturer may gather and review data and literature to determine if the medical benefits of the intended use outweigh the residual risk." Clause 7 of ISO 14971 says: "If the overall residual risk is not judged acceptable using the criteria established in the risk management plan, the manufacturer may gather and review data and literature to determine if the medical benefits of the intended use outweigh the overall residual risk." Both quotes imply that an overall risk-benefit analysis does not need to take place if the overall residual risk is judged acceptable when using the criteria established in the risk management plan. Equally, D.6.1 says: "A risk/benefit analysis is not required by this International Standard for every risk."
b) According to Section 1 of Annex I to Directive 93/42/EEC, an overall risk-benefit analysis must take place in any case, regardless of the application of criteria established in the management plan of the manufacturer. Furthermore, Section 6 of Annex I to Directive 93/42/EEC requires undesirable side-effects to "constitute an acceptable risk when weighed against the performance intended".
c) Accordingly, the manufacturer must undertake the risk-benefit analysis for the individual risk and the overall risk-benefit analysis (weighing all risks combined against the benefit) in all cases.

5. Discretion as to the risk control options/measures:

a) 6.2 of ISO 14971 obliges the manufacturer to "use one or more of the following risk control options in the priority order listed: (a) inherent safety by design; (b) protective measures in the medical device itself or in the manufacturing process; (c) information for safety" and leaves a discretion as to the application of these three options: shall the second or third control option still be used when the first was used? 6.4 indicates that further risk control measures do not need to be taken if, after applying one of the control options, the risk is judged acceptable according to the criteria of the risk management plan.
b) However, the second sentence of Section 2 of Annex I to Directive 93/42/EEC requests "to conform to safety principles, taking account of the generally acknowledged state of the art" and "to select the most appropriate solutions" by applying *cumulatively* what has been called "control options" or "control mechanisms" in the standard.
c) Accordingly, the manufacturer must apply all the "control options" and may not stop his endeavours if the first or the second control option has reduced the risk to an "acceptable level" (unless the additional control option(s) do(es) not improve the safety).

6. Deviation as to the first risk control option:

a) 6.2 of ISO 14971 obliges the manufacturer to "use one or more of the following risk control options in the priority order listed: (a) inherent safety by design …" without determining what is meant by this term.
b) However, the first indent of the second sentence of Section 2 of Annex I to Directive 93/42/EEC requires to "eliminate or reduce risks as far as possible (inherently safe design and construction)".
c) Accordingly, as the Directive is more precise than the standard, manufacturers must apply the former and cannot rely purely on the application of the standard.

7. Information of the users influencing the residual risk:

a) The residual risk is in 2.15 and in 6.4 of ISO 14971 defined as the risk remaining after application of the risk control measures. 6.2 of ISO 14971 regards "information for safety" to be a control option.

b) However, the last indent of Section 2 of Annex I to Directive 93/42/EEC says that users shall be informed about the residual risks. This indicates that, according to Annex I to Directive 93/42/EEC and contrary to the concept of the standard, the information given to the users does not reduce the (residual) risk any further.
c) Accordingly, manufacturers shall not attribute any additional risk reduction to the information given to the users.

Conformity assessment procedures

EN ISO 14971 can also be used to support the following parts of conformity assessment procedures in the European Medical Devices Directives:

– an adequate description of results of the risk analysis (included in the risk management file, see 3.5 of EN ISO 14971:2012);

– an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action (see Clause 9 of EN ISO 14971:2012).

NOTE Other and more detailed requirements are applicable to this aspect.

WARNING — Other requirements and other EU Directives may be applicable to a product falling within the scope of this standard.

Annex ZB
(informative)

Relationship between this European Standard and Requirements of EU Directive 90/385/EEC on Active Implantable Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Requirements of the New Approach Directive 90/385/EEC on Active Implantable Medical Devices.

Within the limits of the scope of this standard (Clause 1 of EN ISO 14971:2012), compliance with the clauses of this standard confers a presumption of conformity with requirements of that Directive and associated EFTA regulations, once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State. This Annex ZB explains to which requirements, under which conditions and to what extent presumption of conformity can be claimed.

Whilst only a limited number of requirements is covered just by the application of this standard, authorities in charge of medical devices strongly recommend using this standard. The standard leads, according to experience of the authorities, to a higher degree of compliance with legal obligations.

EN ISO 14971:2012 provides a process for managing risks associated with medical devices. Because this standard describes an ongoing, lifecycle process applicable in part or in all to the Essential Requirements of Directive 90/385/EEC on Active Implantable Medical Devices, it is – very exceptionally – not meaningful to link individual clauses of the standard to specific corresponding Essential Requirements.

Compliance with all the normative clauses in EN ISO 14971 will ensure that a process is in place to address general risk management aspects related to medical devices, which are included in the Essential Requirements. However, because this is an International Standard, intended to be applicable in jurisdictions all over the world, it is not the primary goal of the standard to cover exactly any of the European Essential Requirements. Therefore, for all of the Essential Requirements, conformity is not entirely achieved by complying only with the requirements specified in this standard. Manufacturers and conformity assessment bodies will need to feed the Essential Requirements into the risk management process provided by the standard. Explanation on the correspondence of the standard and the Essential Requirements is included in Table ZB.1. Further explanation on content deviations between the standard and the ERs is provided below the table.

Table ZB.1 — Correspondence between this European Standard and Directive 90/385/EEC

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 90/385/EEC	Qualifying remarks/Notes
1-9	1	ER 1 is not directly covered by EN ISO 14971, since the standard does not provide requirements on design and manufacture. However, the standard provides a tool to generate the information that is a necessary preliminary step for a manufacturer to demonstrate that the device is in conformity with ER 1. For content deviations, see points 1, 2, 3 below.

1-9	3	ER 3 is not directly covered by EN ISO 14971, since the standard does not apply the concept of 'safety principles' as intended in the AIMDD. However, the standard provides a tool to generate the information that is a necessary preliminary step for a manufacturer to demonstrate that the device is in conformity with ER 3.
1-9	4	ER 4 is not directly covered by EN ISO 14971, since the standard does not provide requirements on design, manufacture or packaging. However, the standard provides a tool to generate the information that is a necessary preliminary step for a manufacturer to demonstrate that the device is in conformity with ER 4.
6.4, 6.5 and 7	5	ER 5 is covered. However, for content deviations, see points 1, 2, 3, 4 below.
1-9	6	ER 6 is not directly covered by EN ISO 14971, since the standard does not provide requirements on design and construction, nor does it apply the concept of 'safety principles' as intended in the AIMDD. However, the standard provides a tool to generate the information that is a necessary preliminary step for a manufacturer to demonstrate that the device is in conformity with ER 6. For content deviations, see point 3 below.
1-9	9	ER 9 is only partly covered by EN ISO 14971, since the standard does not provide requirements on design and manufacture and does not cover performances and characteristics related thereto. Furthermore, it does not provide specific requirements on the items that must be paid particular attention. However, the standard provides a tool to generate the information that is a necessary preliminary step for a manufacturer to demonstrate that the device is in conformity with ER 9. For content deviations, see points 1 to 4 below.

Content deviations

The following aspects have been identified where the standard deviates or might be understood as deviating from the Essential Requirements:

1. Treatment of negligible risks:

a) According to ISO 14971, the manufacturer may discard negligible risks[4].
b) However, Sections 1 and 6 of Annex I to Directive 90/385/EEC require that all risks, regardless of their dimension, need to be reduced as much as possible.
c) Accordingly, the manufacturer must take all risks into account when assessing Sections 1 and 6 of Annex I to Directive 90/385/EEC.

2. Discretionary power of manufacturers as to the acceptability of risks:

a) ISO 14971 seems to imply that manufacturers have the freedom to decide upon the threshold for risk acceptability[5] and that only non-acceptable risks have to be integrated into the overall risk-benefit analysis[6].
b) However, Sections 1 and 6 of Annex I to Directive 90/385/EEC require that all risks have to be reduced as far as possible.
c) Accordingly, the manufacturer may not apply any criteria of risk acceptability prior to applying Sections 1 and 6 of Annex I to Directive 90/385/EEC.

3. Risk reduction "as far as possible" versus "as low as reasonably practicable":

a) D.8 of ISO 14971, referred to in 3.4, contains the concept of reducing risks "as low as reasonably practicable" (ALARP concept). The ALARP concept contains an element of economic consideration.
b) However, various Essential Requirements require risks to be reduced "as far as possible" without there being room for economic considerations.
c) Accordingly, manufacturers and Notified Bodies may not apply the ALARP concept with regard to economic considerations.

4. Discretion as to whether a risk-benefit analysis needs to take place:

a) 6.5 of ISO 14971 says: "If the residual risk is not judged acceptable using the criteria established in the risk management plan and further risk control is not practicable, the manufacturer may gather and review data and literature to determine if the medical benefits of the intended use outweigh the residual risk." Clause 7 of ISO 14971 says: "If the overall residual risk is not judged acceptable using the criteria established in the risk management plan, the manufacturer may gather and review data and literature to determine if the medical benefits of the intended use outweigh the overall residual risk." Both quotes imply that an overall risk-benefit analysis does not need to take place if the overall residual risk is judged acceptable when using the criteria established in the risk management plan. Equally, D.6.1 says: "A risk-benefit analysis is not required by this International Standard for every risk."
b) Section 5 of Annex I to Directive 90/385/EEC requires any side effects or undesirable conditions to "constitute acceptable risks when weighed against the performances intended", implying that an overall risk-benefit analysis must take place in any case, regardless of the application of criteria established in the management plan of the manufacturer.
c) Accordingly, the manufacturer must undertake the risk-benefit analysis for the individual risk and the overall risk-benefit analysis (weighing all risks combined against the benefit) in all cases.

[4] This is explicitly stated in D.8.2.

[5] Sections 5, 6.4, 6.5, 7: reference to the criteria set-up in the management plan which is under the discretion of the manufacturer (see Sections 3.2, 3.4d)). See also D.4: "This International Standard does not specify acceptable risk. That decision is left to the manufacturer."

[6] See D.6.1.

Conformity assessment procedures

EN ISO 14971 can also be used to support the following parts of conformity assessment procedures in the European Medical Devices Directives:

- an adequate description of results of the risk analysis (included in the risk management file, see 3.5 of EN ISO 14971:2012);
- an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action (see Clause 9 of EN ISO 14971:2012).

NOTE Other and more detailed requirements are applicable to this aspect.

WARNING — Other requirements and other EU Directives may be applicable to a product falling within the scope of this standard.

Annex ZC
(informative)

Relationship between this European Standard and Requirements of 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 and the European Free Trade Association to provide a means of conforming to Requirements of the New Approach Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices.

Within the limits of the scope of this standard (Clause 1 of EN ISO 14971:2012), compliance with the clauses of this standard confers a presumption of conformity with requirements of that Directive and associated EFTA regulations, once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State. This Annex ZC explains to which requirements, under which conditions and to what extent presumption of conformity can be claimed.

Whilst only a limited number of requirements is covered just by the application of this standard, authorities in charge of medical devices strongly recommend using this standard. The standard leads, according to experience of the authorities, to a higher degree of compliance with legal obligations.

EN ISO 14971:2012 provides a process for managing risks associated with medical devices. Because this standard describes an ongoing, lifecycle process applicable in part or in all to the Essential Requirements of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices, it is – very exceptionally – not meaningful to link individual clauses of the standard to specific corresponding Essential Requirements.

Compliance with all the normative clauses in EN ISO 14971 will ensure that a process is in place to address general risk management aspects related to medical devices, which are included in the Essential Requirements. However, because this is an International Standard, intended to be applicable in jurisdictions all over the world, it is not the primary goal of the standard to cover exactly any of the European Essential Requirements. Therefore, for all of the Essential Requirements, conformity is not entirely achieved by complying only with the requirements specified in this standard. Manufacturers and conformity assessment bodies will need to feed the Essential Requirements into the risk management process provided by the standard. Explanation on the correspondence of the standard and the Essential Requirements is included in Table ZC.1. Further explanation on content deviations between the standard and the ERs is provided below the table.

Table ZC.1 — Correspondence between this European Standard and Directive 98/79/EEC

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying remarks/Notes
1-9	A.1	ER A.1 is not directly covered by EN ISO 14971, since the standard does not provide requirements on design and manufacture. However, the standard provides a tool to generate the information that is a necessary preliminary step for a manufacturer to demonstrate that the device is in conformity with ER A.1. For content deviations, see points 1, 2, 3, 4 below.
1-9	A.2	- The second sentence of ER A.2 is partly covered by 6.2. For content

		deviations, see points 1, 2, 3, 5, 6, 7 below. - The other parts of ER A.2 are not directly covered by EN ISO 14971, since the standard does not provide requirements on design and construction, nor does it apply the concept of 'safety principles' as intended in the IVDD. However, the standard provides a tool to generate the information that is a necessary preliminary step for a manufacturer to demonstrate that the device is in conformity with ER A.2.
1-9	A.4	ER A.4 is not directly covered by EN ISO 14971, since the standard does not apply the concept of 'safety principles' as intended in the IVDD. However, the standard provides a tool to generate the information that is a necessary preliminary step for a manufacturer to demonstrate that the device is in conformity with ER A.4.
1-9	A.5	ER A.5 is not directly covered by EN ISO 14971, since the standard does not provide requirements on design, manufacture or packaging. However, the standard provides a tool to generate the information that is a necessary preliminary step for a manufacturer to demonstrate that the device is in conformity with ER A.5.
1-9	B.1.1	ER B.1.1 is only partly covered by EN ISO 14971, since the standard does not provide requirements on design and manufacture and does not cover performances and characteristics related thereto. Furthermore, it does not provide specific requirements on the items that must be paid particular attention. However, the standard provides a tool to generate the information that is a necessary preliminary step for a manufacturer to demonstrate that the device is in conformity with ER B.1.1. For content deviations, see points 1 to 7 below.