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Medical devices — Application of risk management to medical devices

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About Tracked Changes

This document is a PDF containing a Tracked Changes version of BS EN ISO 14971, which compares BS EN ISO 14971:2019 with BS EN ISO 14971:2012.

The original version of BS EN ISO 14971:2019, appended at the end of this document, should be considered the version of record for this publication.

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National foreword

This British Standard is the UK implementation of ~~EN ISO 14971:2012.~~EN ISO 14971:2019. It is identical to ~~ISO 14971:2007.~~ISO 14971:2019. It supersedes ~~BS EN ISO 14971:2009~~BS EN ISO 14971:2012, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/210/4, Risk analysis for Medical Devices.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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Supersedes EN ISO 14971:~~2009~~2012

English version

Medical devices - Application of risk management to medical devices (ISO 14971:~~2007~~2019~~, Corrected version 2007-10-01~~)

Dispositifs médicaux - Application de la gestion des risques aux dispositifs médicaux
(ISO 14971:~~2007~~2019~~, Version corrigée de 2007-10-01~~)

Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte
(ISO 14971:~~2007~~2019~~, korrigierte Fassung 2007-10-01~~)

This European Standard was approved by CEN on ~~16 May 2012~~5 August 2019.

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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.

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CEN-CENELEC Management Centre:
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~~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.~~

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	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.

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)".

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.

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	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.

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.

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[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.

~~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.~~

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

		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.

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[7].
b) However, Sections A.1 and A.2 of Annex I to Directive 98/79/EC 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 A.1 and A.2 of Annex I to Directive 98/79/EC.

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[8] and that only non-acceptable risks have to be integrated into the overall risk-benefit analysis[9].
b) However, Sections A.1 and A.2 of Annex I to Directive 98/79/EC 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 A.1 and A.2 of Annex I to Directive 98/79/EC.

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

a) 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 A.2 of Annex I to Directive 98/79/EC 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 A.1 of Annex I to Directive 98/79/EC, 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 overall risk-benefit analysis (weighing all risks combined against the benefit) in all cases.

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[7] This is explicitly stated in D.8.2.
[8] 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."
[9] See D.6.1.

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 A.2 of Annex I to Directive 98/79/EC 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 A.2 of Annex I to Directive 98/79/EC 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 A.2 of Annex I to Directive 98/79/EC says that users shall be informed about the residual risks. This indicates that, according to Annex I to Directive 98/79/EC 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.

This document (EN ISO 14971:2019) has been prepared by Technical Committee ISO/TC 210 "Quality management and corresponding general aspects for medical devices" in collaboration with Technical Committee CEN/CLC/JTC 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 June 2020, and conflicting national standards shall be withdrawn at the latest by June 2020.

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 14971:2012.

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.

Endorsement notice

The text of ISO 14971:2019 has been approved by CEN as EN ISO 14971:2019 without any modification.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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).

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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.

International Standard ISO 14971 was prepared by This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and Subcommittee IEC/SC 62A, *Common aspects of electrical equipment used in medical practice*. Annex H, "Guidance on risk management for *in vitro* diagnostic medical devices", was prepared by ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This second edition cancels and replaces the first edition (ISO 14971:2000) as well as the amendment ISO 14971:2000/Amd.1:2003.

For purposes of future IEC maintenance, Subcommittee 62A has decided that the contents of this publication will remain unchanged until the maintenance result date[1] indicated on the IEC web site under http://webstore.iec.ch in the data related to the specific publication. At this date, the publication will be

— reconfirmed,

— withdrawn,

— replaced by a revised edition or

— amended.

This corrected version of ISO 14971:2007 incorporates the following correction:

— a corrected version of Figure 1 on page 6.

1) IEC National Committees are requested to note that for this publication the maintenance result date is 2014.

This third edition cancels and replaces the second edition (ISO 14971:2007), which has been technically revised. The main changes compared to the previous edition are as follows:

— A clause on normative references has been included, in order to respect the requirements for fixed in Clause 15 of ISO/IEC Directives, Part 2:2018.

— The defined terms are updated and many are derived from ISO/IEC Guide 63:2019. Defined terms are printed in italic to assist the reader in identifying them in the body of the document.

— Definitions of *benefit*, *reasonably foreseeable misuse* and *state of the art* have been introduced.

— More attention is given to the *benefits* that are expected from the use of the *medical device*. The term *benefit-risk* analysis has been aligned with terminology used in some regulations.

— It is explained that the *process* described in ISO 14971 can be used for managing *risks* associated with *medical devices*, including those related to data and systems security.

— The method for the evaluation of the overall *residual risk* and the criteria for its acceptability are required to be defined in the *risk management* plan. The method can include gathering and reviewing data and literature for the *medical device* and for similar *medical devices* and similar other products on the market. The criteria for the acceptability of the overall *residual risk* can be different from the criteria for acceptability of individual *risks*.

— The requirements to disclose *residual risks* have been moved and merged into one requirement, after the overall *residual risk* has been evaluated and judged acceptable.

— The review before commercial distribution of the *medical device* concerns the execution of the *risk management* plan. The results of the review are documented as the *risk management* report.

— The requirements for production and *post-production* activities have been clarified and restructured. More detail is given on the information to be collected and the actions to be taken when the collected information has been reviewed and determined to be relevant to *safety*.

— Several informative annexes are moved to the guidance in ISO/TR 24971, which has been revised in parallel. More information and a rationale for the requirements in this third edition of ISO 14971 have been provided in Annex A. The correspondence between the clauses of the second edition and those of this third edition is given in Annex B.

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.

The requirements contained in this ~~International Standard~~document provide *manufacturers* with a framework within which experience, insight and judgment are applied systematically to manage the *risks* associated with the use of *medical devices*.

This ~~International Standard~~document was developed specifically for ~~medical device/system~~ *manufacturers* ~~*using*~~of *medical devices* on the basis of established principles of *risk management*~~. For other manufacturers, e.g., in other healthcare industries, this International Standard~~ that have evolved over many years. This document could be used as ~~informative~~ guidance in developing and maintaining a *risk management* ~~*system and*~~ *process* for other products that are not necessarily *medical devices* in some jurisdictions and for suppliers and other parties involved in the *medical device life cycle*.

This ~~International Standard~~document deals with *processes* for managing *risks*~~, primarily~~ associated with *medical devices*. *Risks* can be related to injury, not only to the patient, but also to the ~~operator,~~ user and other persons. *Risks* can also be related to damage to property (for example objects, data, other equipment~~ and~~) or the environment.

~~*As a general concept, activities in which an individual, organization or government is involved can expose those or other stakeholders to hazards which can cause loss of or damage to something they value.*~~ *Risk management* is a complex subject because each stakeholder ~~places~~can place a different value on the ~~probability of harm occurring and its severity.~~acceptability of *risks* in relation to the anticipated *benefits*.

~~It is accepted that the concept of risk has two components:~~

~~a) the probability of occurrence of harm;~~

~~b) the consequences of that harm, that is, how severe it might be.~~

The concepts of *risk management* are particularly important in relation to *medical devices* because of the variety of stakeholders including medical practitioners, the organizations providing health care, governments, industry, patients and members of the public.

It is generally accepted that the concept of *risk* has two key components:

— the probability of occurrence of *harm*; and

— the consequences of that *harm*, that is, how severe it might be.

All stakeholders need to understand that the use of a *medical device* ~~*entails some*~~ involves an inherent degree of *risk*, even after the *risks* have been reduced to an acceptable level. It is well known that in the context of a clinical *procedure* some *residual risks* remain. The acceptability of a *risk* to a stakeholder is influenced by the key components listed above and by the stakeholder's perception of the *risk* and the *benefit*. Each stakeholder's perception ~~of the risk~~ can vary~~ greatly~~ depending upon their cultural background, the socio-economic and educational background of the society concerned and the actual and perceived state of health of the patient~~, and many other factors.~~. The way a *risk* is perceived also takes into account other factors, for example, whether exposure to the *hazard* or *hazardous situation* seems to be involuntary, avoidable, from a man-made source, due to negligence, arising from a poorly understood cause, or directed at a vulnerable group within society.~~ The decision to use a medical device in the context of a particular clinical procedure requires the residual risks to be balanced against the anticipated benefits of the procedure. Such judgments should take into account the intended use, performance and risks associated with the medical device, as well as the risks and benefits associated with the clinical procedure or the circumstances of use. Some of these judgments can be made only by a qualified medical practitioner with knowledge of the state of health of an individual patient or the patient's own opinion.~~

As one of the stakeholders, the *manufacturer* reduces *risks* and makes judgments relating to the *safety* of a *medical device*, including the acceptability of *residual risks*~~, taking~~. The *manufacturer* takes into account the generally ~~accepted~~acknowledged *state of the art*, in order to determine the suitability of a *medical device* to be placed on the market for its *intended use*. This ~~International Standard~~document specifies a *process* through which the *manufacturer* of a *medical device* can identify *hazards* associated with ~~a~~the *medical device*, estimate and evaluate the *risks* associated with these *hazards*, control these *risks*, and monitor the effectiveness of ~~that control~~the controls throughout the *life cycle* of the *medical device*.

risks to be balanced against the anticipated *benefits* of the *procedure*. Such decisions are beyond the scope of this document and take into account the *intended use*, the circumstances of use, the performance and *risks* associated with the *medical device*, as well as the *risks* and *benefits* associated with the clinical *procedure*. Some of these decisions can be made only by a qualified medical practitioner with knowledge of the state of health of an individual patient or the patient's own opinion.

For any particular *medical device*, other ~~International Standards~~ standards or regulations could require the application of specific methods for managing *risk*. In those cases, it is necessary to also follow the requirements outlined in those documents.

The verbal forms used in this document conform to the usage described in Clause 7 of the ISO/ IEC Directives, Part 2:2018. For the purposes of this document, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

— "may" is used to describe permission (e.g. a permissible way to achieve compliance with a requirement or test);

— "can" is used to express possibility and capability; and

— "must" is used to express an external constraint that is not a requirement of the document.

Medical devices — Application of risk management to medical devices

1 Scope

This ~~International Standard~~document specifies terminology, principles and a *process* for ~~a manufacturer to~~ *risk management* of *medical devices*, including software as a *medical device* and *in vitro diagnostic medical devices*. The *process* described in this document intends to assist *manufacturers* of *medical devices* to identify the *hazards* associated with ~~medical devices, including *in vitro* diagnostic (IVD) medical devices~~the *medical device*, to estimate and evaluate the associated *risks*, to control these *risks*, and to monitor the effectiveness of the controls.

The requirements of this ~~International Standard~~document are applicable to all ~~stages~~phases of the *life cycle* of a *medical device*. The *process* described in this document applies to *risks* associated with a *medical device*, such as *risks* related to biocompatibility, data and systems security, electricity, moving parts, radiation, and usability.

The *process* described in this document can also be applied to products that are not necessarily *medical devices* in some jurisdictions and can also be used by others involved in the *medical device life cycle*.

~~This International Standard does not apply to clinical decision making.~~

~~This International Standard does not specify acceptable *risk* levels.~~

~~*This International Standard* does not require that the *manufacturer* have a quality management system in place. However, risk management can be an integral part of a quality management system.~~

This document does not apply to:

— decisions on the use of a *medical device* in the context of any particular clinical *procedure*; or

— business *risk management*.

This document requires *manufacturers* to establish objective criteria for *risk* acceptability but does not specify acceptable *risk* levels.

Risk management can be an integral part of a quality management system. However, this document does not require the *manufacturer* to have a quality management system in place.

NOTE Guidance on the application of this document can be found in ISO/TR 24971[9].

2 Normative references

There are no normative references in this document.

~~2~~3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available athttps://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/