SLOVENSKI STANDARD
SIST EN 60601-1:2007/A2:2021

01-december-2021

Medicinska električna oprema - 1. del: Splošne zahteve za osnovno varnost in bistvene zmogljivosti - Dopolnilo A2 (IEC 60601-1:2005/A2:2020)

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005/A2:2020)

Medizinische elektrische Geräte - Teil 1: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale (IEC 60601-1:2005/A2:2020)

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Appareils électromédicaux - Partie 1: Exigences générales pour la sécurité de base et les performances essentielles (IEC 60601-1:2005/A2:2020)

SIST EN 60601-1:2007/A2:2021
https://standards.iteh.ai/catalog/standards/sist/0257cbf1-9537-456f-b056-c6e7439e0f8a/sist-en-60601-1-2007-a2-2021

Ta slovenski standard je istoveten z: **EN 60601-1:2006/A2:2021**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN 60601-1:2007/A2:2021 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

SIST EN 60601-1:2007/A2:2021

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SIST EN 60601-1:2007/A2:2021
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SIST EN 60601-1:2007/A2:2021

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1:2006/A2

October 2021

ICS 11.040.01

English Version

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005/A2:2020)

Appareils électromédicaux - Partie 1: Exigences générales pour la sécurité de base et les performances essentielles (IEC 60601-1:2005/A2:2020)

Medizinische elektrische Geräte - Teil 1: Allgemeine Festlegungen für die Basissicherheit einschließlich der wesentlichen Leistungsmerkmale (IEC 60601-1:2005/A2:2020)

This amendment A2 modifies the European Standard EN 60601-1:2006; it was approved by CENELEC on 2020-09-24. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 CENELEC member.

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

SIST EN 60601-1:2007/A2:2021
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c667459c018a/sist-en-60601-1-2007-a2-2021

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Ref. No. EN 60601-1:2006/A2:2021 E

SIST EN 60601-1:2007/A2:2021

European foreword

The text of document 62A/1389/FDIS, future IEC 60601-1/A2, prepared by SC 62A "Common aspects of electrical equipment used in medical practice" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-1:2006/A2:2021.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2022-04-08
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2024-10-08

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

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The text of the International Standard IEC 60601-1:2005/A2:2020 was approved by CENELEC as a European Standard without any modification.

SIST EN 60601-1:2007/A2:2021
https://standards.iteh.ai/catalog/standards/sist/0357cbf3-953f-456f-b05d-c6e7439e0f8a/sist-en-60601-1-2007-a2-2021

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-2-57	NOTE	Harmonized as EN 60601-2-57
IEC 62366-1:2015	NOTE	Harmonized as EN 62366-1:2015 (not modified)
ISO 2409	NOTE	Harmonized as EN ISO 2409
ISO 4624	NOTE	Harmonized as EN ISO 4624
ISO 10524-1:2018	NOTE	Harmonized as EN ISO 10524-1:2019 (not modified)
ISO 13732-1:2006	NOTE	Harmonized as EN ISO 13732-1:2008 (not modified)

SIST EN 60601-1:2007/A2:2021

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Replace Annex ZA by the following one:

Publication	Year	Title	EN/HD	Year
IEC 60065	2001	Audio, video and similar electronic apparatus - Safety requirements	-	-
+ A1	2005		-	-
+ A2	2010		-	-
IEC 60068-2-2	2007	Environmental testing - Part 2-2: Tests - Test B: Dry heat	EN 60068-2-2	2007
IEC 60079-0	-	Explosive atmospheres - Part 0: Equipment - General requirements	EN IEC 60079-0	-
IEC 60079-2	-	Explosive atmospheres - Part 2: Equipment protection by pressurized enclosure "p"	EN 60079-2	-
IEC 60079-5	-	Explosive atmospheres - Part 5: Equipment protection by powder filling "q"	EN 60079-5	-
IEC 60079-6	-	Explosive atmospheres - Part 6: Equipment protection by liquid immersion "o"	EN 60079-6	-
IEC 60083	-	Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC	-	-
IEC 60085	-	Electrical insulation - Thermal evaluation and designation	EN 60085	-
IEC 60086-4	-	Primary batteries - Part 4: Safety of lithium batteries	EN IEC 60086-4	-
IEC 60112	-	Method for the determination of the proof and the comparative tracking indices of solid insulating materials	EN IEC 60112	-
IEC 60127-1	-	Miniature fuses - Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links	EN 60127-1	-
IEC 60227-1	2007	Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V - Part 1: General requirements	-	-

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SIST EN 60601-1:2007/A2:2021

Publication	Year	Title	EN/HD	Year
IEC 60245-1	2003	Rubber insulated cables - Rated voltages up to and including 450/750 V -- Part 1: General requirements	-	-
+ A1	2007		-	-
IEC 60252-1	-	AC motor capacitors - Part 1: General - Performance, testing and rating - Safety requirements - Guidance for installation and operation	EN 60252-1	-
IEC 60320-1	-	Appliance couplers for household and similar general purposes - Part 1: General requirements	EN 60320-1	-
IEC 60335-1 (mod)	2010	Household and similar electrical appliances - Safety - Part 1: General requirements	EN 60335-1	2012
-	-		+ A11	2014
-	-		+ AC	2014
-	-		+ A13	2017
-	-		+ A14	2019
-	-		+ A15	2021
IEC 60364-4-41	-	Low-voltage electrical installations - Part 4-41: Protection for safety - Protection against electric shock	HD 60364-4-41	-
IEC 60384-14	2005	Fixed capacitors for use in electronic equipment -- Part 14: Sectional specification - Fixed capacitors for electromagnetic interference suppression and connection to the supply mains	-	-
IEC 60417	-	Graphical symbols for use on equipment. Index, survey and compilation of the single sheets.	-	-
IEC 60445	-	Basic and safety principles for man-machine interface, marking and identification – Identification of equipment terminals and of terminations of certain designated conductors, including general rules for an alphanumeric system	-	-
IEC 60447	-	Basic and safety principles for man-machine interface, marking and identification - Actuating principles	EN 60447	-
IEC 60529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529	1991
-	-		+ corrigendum May	1993
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	2015
+ A1	2020		+ A1	2021
IEC 60601-1-3	2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	EN 60601-1-3	2008

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SIST EN 60601-1:2007/A2:2021

Publication	Year	Title	EN/HD	Year
-	-		+ corrigendum Mar.	2010
+ A1	2013		+ A1	2013
-	-		+ AC	2014
-	-		+ A11	2016
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
+ A1	2013		+ A1	2015
+ A2	2020		+ A2	2021
IEC 60601-1-8	2006	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	-	-
+ A1	2012		+ A1	2013
-	-		+ AC	2014
+ A2	2020		+ A2	2021
IEC 60664-1	2007	Insulation coordination for equipment within low-voltage systems - Part 1: Principles, requirements and tests	EN 60664-1	2007
IEC 60695-11-10	-	Fire hazard testing - Part 11-10: Test flames - 50 W horizontal and vertical flame test methods	EN 60695-11-10	-
IEC 60730-1 (mod)	2010	Automatic electrical controls for household and similar use -- Part 1: General requirements	EN 60730-1	2011
IEC 60747-5-5	2007	Semiconductor devices - Discrete devices - Part 5-5: Optoelectronic devices - Photocouplers	EN 60747-5-5	2011
IEC 60825-1	2014	Safety of laser products - Part 1: Equipment classification and requirements	EN 60825-1	2014
-	-		+ A11	2021
-	-		/AC	2017
IEC 60851-3	2009	Winding wires - Test methods - Part 3: Mechanical properties	EN 60851-3	2009
IEC 60851-5	2008	Winding wires - Test methods - Part 5: Electrical properties	EN 60851-5	2008
IEC 60851-6	1996	Winding wires - Test methods -- Part 6: Thermal properties	-	-
IEC 60884-1	-	Plugs and socket-outlets for household and similar purposes -- Part 1: General requirements	-	-
IEC 60950-1	2005	Information technology equipment - Safety - Part 1: General requirements	-	-
+ A1	2009		-	-
+ A2	2013		-	-

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SIST EN 60601-1:2007/A2:2021

Publication	Year	Title	EN/HD	Year
IEC 61058-1	2000	Switches for appliances -- Part 1: General requirements	-	-
+ A1	2001		-	-
+ A2	2007		-	-
IEC 61558-2-1	-	Safety of power transformers, power supplies, reactors and similar products - Part 2-1: Particular requirements and tests for separating transformers and power supplies incorporating separating transformers for general applications	EN 61558-2-1	-
IEC 61672-1	-	Electroacoustics - Sound level meters - Part 1: Specifications	EN 61672-1	-
IEC 61672-2	-	Electroacoustics - Sound level meters - Part 2: Pattern evaluation tests	EN 61672-2	-
IEC 61965	-	Mechanical safety of cathode ray tubes	EN 61965	-
IEC 62133	-	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications	-	-
IEC 62133-2	-	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems	EN 62133-2	-
IEC 62304	2006	Medical device software - Software life cycle processes	EN 62304	2006
-	-		+ corrigendum Nov.	2008
IEC 62368-1	2018	Audio/video, information and communication technology equipment - Part 1: Safety requirements	EN IEC 62368-1	2020
ISO 780	-	Packaging – Pictorial marking for handling of goods	EN ISO 780	-
ISO 1853	-	Conducting and dissipative rubbers, vulcanized or thermoplastic - Measurement of resistivity	-	-
ISO 2878	-	Rubber, vulcanized or thermoplastic - Antistatic and conductive products - Determination of electrical resistance	-	-
ISO 2882	-	Rubber, vulcanized - Antistatic and conductive products for hospital use - Electrical resistance limits	-	-
ISO 3746	-	Acoustics - Determination of sound power levels and sound energy levels of noise sources using sound pressure - Survey method using an enveloping measurement surface over a reflecting plane	EN ISO 3746	-

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SIST EN 60601-1:2007/A2:2021

Publication	Year	Title	EN/HD	Year
ISO 3864-1	2002	Graphical symbols - Safety colours and safety signs – Part 1: Design principles for safety signs in workplaces and public areas	-	-
ISO 5349-1	-	Mechanical vibration - Measurement and evaluation of human exposure to hand-transmitted vibration – Part 1: General requirements	EN ISO 5349-1	-
ISO 7000	-	Graphical symbols for use on equipment - Registered symbols	-	-
ISO 7010	2019	Graphical symbols - Safety colours and safety signs - Registered safety signs	-	-
ISO 9614-1	-	Acoustics - Determination of sound power levels of noise sources using sound intensity - Part 1: Measurement at discrete points	EN ISO 9614-1	-
ISO 10993	series	Biological evaluation of medical devices	EN ISO 10993	series
ISO 11135-1	2007	Sterilization of health care products - Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	-	-
ISO 11137-1	2006	Sterilization of health care products - Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	EN ISO 11137-1	2015
ISO 13857	2008	Safety of machinery - Safety distances to prevent hazard zones being reached by upper and lower limbs	-	-
ISO 14971	2019	Medical devices – Application of risk management to medical devices	EN ISO 14971	2019
ISO 15223-1	2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	EN ISO 15223-1	2016
ISO 17665-1	2006	Sterilization of health care products - Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	EN ISO 17665-1	2006
ISO 23529	-	Rubber - General procedures for preparing and conditioning test pieces for physical test methods	-	-
ISO 80000-1	2009	Quantities and units -- Part 1: General	EN ISO 80000-1	2013

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IEC 60601-1

Edition 3.0 2020-08

INTERNATIONAL STANDARD

colour inside

AMENDMENT 2

Medical electrical equipment –
Part 1: General requirements for basic safety and essential performance

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SIST EN 60601-1:2007/A2:2021

FOREWORD

This amendment has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62A/1389/FDIS	62A/1404/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date 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.

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NOTE The attention of the users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

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IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

SIST EN 60601-1:2007/A2:2021

INTRODUCTION TO AMENDMENT 2

The third edition of IEC 60601-1 was published in 2005 and amended in 2012. Since the publication of IEC 60601-1:2005/AMD1:2012, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees and questions submitted to IEC/SC 62A/Working Group (WG) 14. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in Amendment 2 and should not wait until the fourth edition of IEC 60601-1, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 2 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, 109 items were presented to the National Committees present. A total of 78 items received the required 2/3 majority of the National Committees present and voting and were included in the "short list" for consideration in preparing Amendment 2. All remaining issues have been placed on a "long list" for consideration in the fourth edition of IEC 60601-1.

The "short list" of issues was documented in the design specification for Amendment 2. The responsible expert groups were directed to consider each issue assigned to it in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the standard was justified by the problem statement.

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Because this is an amendment to the 2005 edition of IEC 60601-1, the style in force at the time of publication of IEC 60601-1 has been applied to this amendment. The style specified in ISO/IEC Directives, Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes. For example, notes to definitions are designated as "NOTE" rather than "Note to entry" in Clause 3.

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Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

SIST EN 60601-1:2007/A2:2021

INTRODUCTION

Add, after the existing last paragraph, the following paragraph:

Throughout this document, there are many references to, and requirements incorporated from IEC 60950-1. Some of these requirements are derived from IEC 60950-1. For example, the requirements for spaces filled by insulating compound in 8.9.3. In other cases, the requirements are incorporated by a normative reference to IEC 60950-1:2005. For example, the requirements for solid insulation forming a MEANS OF OPERATOR PROTECTION in 8.5.1.3. The requirements incorporated by reference are primarily found in Clause 8 of this document, including many of the tables used to determine the requirements for MEANS OF PROTECTION, primarily MEANS OF OPERATOR PROTECTION and INSULATION CO-ORDINATION. The requirements incorporated by reference are addressed in Amendment 2. The derived requirements will be addressed during the development of the fourth edition of this document.

1.3 * Collateral standards

Replace the existing second paragraph with:

Applicable collateral standards shall apply together with this standard.

Delete the existing third paragraph.

1.4 * Particular standards

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Replace the existing first paragraph with:

In the IEC 60601 series, particular standards specify BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for the particular ME EQUIPMENT and ME SYSTEMS. Particular standards may modify, replace or delete requirements contained in this standard and applicable collateral standards as appropriate for the particular ME EQUIPMENT and ME SYSTEMS under consideration.

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Replace the existing second paragraph with:

A requirement of a particular standard takes priority over this standard and applicable collateral standards.

2 * Normative references

Replace the existing second paragraph with:

ATTENTION: Additional collateral standards of the IEC 60601 series, which are issued subsequent to publication of this standard, shall apply together with this standard when applicable. They shall be considered as being included among the normative references below. See 1.3.

Replace the following existing references to IEC 60601-1-2, IEC 60601-1-3 modified by Amendment 1, IEC 60601-1-6 and IEC 60601-1-8 by the following new references:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*
Amendment 1:2020

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*
Amendment 1:2013

SIST EN 60601-1:2007/A2:2021

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
Amendment 1:2013
Amendment 2:2020

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
Amendment 1:2012
Amendment 2:2020

Add the following new reference to the list:

IEC 60747-5-5:2007, *Semiconductor devices – Discrete devices – Part 5-5: Optoelectronic devices – Photocouplers*

Replace, in the existing reference to IEC 60825-1, "2007" *with* "2014".

Replace the existing references to IEC 60950-1 and IEC 62304 by the following new references:

IEC 60950-1:2005, *Information technology equipment – Safety – Part 1: General requirements*
Amendment 1:2009
Amendment 2:2013

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IEC 62304:2006, *Medical device software – Software life cycle processes*
Amendment 1:2015

Add the following normative references to the existing list:

SIST EN 60601-1:2007/A2:2021
https://standards.iteh.ai/catalog/standards/sist/0257cbf1-9537-456f-b056-c0e7439c0f6a/sist-en-60601-1-2007-a2-2021

IEC 62133-2, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems*

IEC 62368-1:2018, *Audio/video, information and communication technology equipment – Part 1: Safety requirements*

Replace the existing references to ISO 7000-DB:2004 by the following new reference:
ISO 7000, *Graphical symbols for use on equipment*

Replace, in the existing reference to ISO 7010, "2011" *with* "2019".

Replace, in the existing reference to ISO 14971, "2007" *with* "2019".

Replace, in the existing reference to ISO 15223-1, "2012" *with* "2016".

3 * Terminology and definitions

3.38
*** HARM**

Replace the existing term and definition, modified by Amendment 1, with:

3.38
*** HARM**
injury or damage to the health of people or animals, or damage to property or the environment

[ISO 14971:2019, definition 3.3, modified – "Or animals" added to the definition.]