

| | | |
|------------|---|---|
| STN | Zdravotnicke elektrické prístroje Časť 1: Všeobecné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti Zmena A2 | STN EN 60601-1/A2 36 4800 |
|------------|---|---|

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/21

STN EN 60601-1 z novembra 2009 sa bez tejto zmeny A2 môže používať do 8. 10. 2024.

Obsahuje: EN 60601-1:2006/A2:2021, IEC 60601-1:2005/AMD2:2020

EUROPEAN STANDARD

EN 60601-1:2006/A2

NORME EUROPÉENNE

EUROPÄISCHE NORM

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.

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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



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

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

EN 60601-1:2006/A2:2021 (E)**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 (dop) 2022-04-08 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2024-10-08 document have to be withdrawn

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

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

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) |

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:

| <u>Publication</u> | <u>Year</u> | <u>Title</u> | <u>EN/HD</u> | <u>Year</u> |
|--------------------|-------------|--|----------------|-------------|
| 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 | - | - |

EN 60601-1:2006/A2:2021 (E)

| <u>Publication</u> | <u>Year</u> | <u>Title</u> | <u>EN/HD</u> | <u>Year</u> |
|--------------------|-------------|--|-------------------|-------------|
| 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 |

EN 60601-1:2006/A2:2021 (E)

| <u>Publication</u> | <u>Year</u> | <u>Title</u> | <u>EN/HD</u> | <u>Year</u> |
|--------------------|-------------|---|-----------------------|-------------|
| - | - | | + 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 | | - | - |

EN 60601-1:2006/A2:2021 (E)

| <u>Publication</u> | <u>Year</u> | <u>Title</u> | <u>EN/HD</u> | <u>Year</u> |
|--------------------|-------------|--|--------------------|-------------|
| 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 | - |

EN 60601-1:2006/A2:2021 (E)

| <u>Publication</u> | <u>Year</u> | <u>Title</u> | <u>EN/HD</u> | <u>Year</u> |
|--------------------|-------------|--|----------------|-------------|
| 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 |



IEC 60601-1

Edition 3.0 2020-08

INTERNATIONAL STANDARD



AMENDMENT 2

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



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IEC Glossary - std.iec.ch/glossary

67 000 electrotechnical terminology entries in English and French extracted from the Terms and definitions clause of IEC publications issued between 2002 and 2015. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.



IEC 60601-1

Edition 3.0 2020-08

INTERNATIONAL STANDARD



AMENDMENT 2

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.01

ISBN 978-2-8322-8632-6

Warning! Make sure that you obtained this publication from an authorized distributor.

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.

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.

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.

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.

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.

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.

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

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.

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

IEC 60601-1:2005/AMD2:2020
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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

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

Add the following normative references to the existing list:

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".

koniec náhľadu – text ďalej pokračuje v platenej verzii STN