# SLOVENSKI STANDARD
# SIST EN 60601-2-33:2010/A12:2017

**01-januar-2017**

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**Medicinska električna oprema - 2-33. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za magnetno resonanco za medicinsko diagnostiko - Dopolnilo A12**

Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis

Medizinische elektrische Geräte - Teil 2-33: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Magnetresonanzgeräten für die medizinische Diagnostik



Appareils électromédicaux - Partie 2-33: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à résonance magnétique utilisés pour le diagnostic médical

**Ta slovenski standard je istoveten z:** **EN 60601-2-33:2010/A12:2016**

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**ICS:**

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|---|---|---|
| 11.040.55 | Diagnostična oprema | Diagnostic equipment |

**SIST EN 60601-2-33:2010/A12:2017** **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

**EN 60601-2-33:2010/A12**

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English Version

# Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis

Appareils électromédicaux - Partie 2-33: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à résonance magnétique utilisés pour le diagnostic médical

Medizinische elektrische Geräte - Teil 2-33: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Magnetresonanzgeräten für die medizinische Diagnostik

This amendment A12 modifies the European Standard EN 60601-2-33:2010; it was approved by CENELEC on 2016-11-01. 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.



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

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## European foreword

This document (EN 60601-2-33:2010/A12:2016) has been prepared by CLC/TC 62 "Electrical equipment in medical practice".

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) 2017-11-01
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2019-11-01

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

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).



For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

## 1 Modifications to annexes

***Replace*** *Annex ZA and Annex ZZ with the following.*

### Annex ZA
(normative)

### Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. However, for any use of this standard “within the meaning of Annex ZZ", the user must always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When the IEC or ISO standard is referred to in the IEC text standard, this must be understood as a normative reference to the parallel EN standard, as outlined below, including the foreword and the Annexes ZZ.



NOTE 1 The way in which referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.



NOTE 2 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.



| Publication | Year | Title | EN/HD and IEC/ISO | Year |
|---|---|---|---|---|
| IEC 60601-1 | 2005 | Medical electrical equipment<br>Part 1: General requirements for basic safety and essential performance | EN 60601-1 | 2006 |
| +A1 | 2012 | | EN 60601-1/A1 | 2013 |
| | | | EN 60601-1/A1/AC | 2014 |
| IEC 60601-1-2 | 2014 | Medical electrical equipment<br>Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests | EN 60601-1-2 | 2015 |
| IEC 60601-1-6 | 2010 | Medical electrical equipment -<br>Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability | EN 60601-1-6 | 2010 |
| +A1 | 2013 | | EN 60601-1-6/A1 | 2015 |
| IEC 60601-1-8 | 2006 | Medical electrical equipment -<br>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 | EN 60601-1-8 | 2007 |
| +A1 | 2012 | | EN 60601-1-8/AC | 2010 |
| | | | EN 60601-1-8/A1 | 2015 |
| IEC 62570 | 2014 | Standard practice for marking medical devices and other items for safety in the magnetic resonance environment | EN 62570 | 2015 |

# Annex ZZ
(informative)

## Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association to provide a means of conforming to the Essential Requirements given in Annex I of EU Directive 93/42/EEC.

**General Guidance:**

Once this standard will be cited in the Official Journal of the European Union under that Directive, compliance with the clauses of this standard given in Table ZZ.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements (ERs) of that Directive and associated EFTA regulations.

NOTE 1 The standard's scope is limited to the specific uses, environments, contexts, objective situations specifically indicated. It cannot provide for presumption of conformity in other conditions. Some clauses or subclauses may be not applicable due to the specific type of equipment under consideration.

NOTE 2 Only prescriptions contained in the normative parts of the text are relevant to the presumption of conformity of this standard. Informative parts may, however, support users to interpret such prescriptions correctly.



NOTE 3 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC. This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement which must be interpreted and applied in such a way as to take account of technology and practice existing at the time of design and of technical and economical considerations compatible with a high level of protection of health and safety.



NOTE 4 The manufacturer's policy for determining **acceptable risk** must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the directive.

NOTE 5 For all parts of this standard that a) refer in their clauses to specific national legislation possibly exempting manufacturers from the thorough application of relevant provisions of this standard or b) link the completion of a relevant process/prescription to any discretional choice/power of manufacturers, the user of the standard should check that such clauses are in compliance with Directive 93/42/EEC.

NOTE 6 This Annex ZZ is based on Normative References according to Annex ZA, replacing the references in the core text.

**WARNING: Other requirements and other EU Directives and Regulations may be applicable to the product(s) falling within the scope of this standard.**

**Table ZZ.1 – Relationship between Essential Requirements of Directive 93/42/EEC amended by 2007/47/EC, and Clauses and subclauses of this standard**

| No. | Essential Requirements | Coverage of EN 60601-2-33 |
|---|---|---|
| **I.** | **GENERAL REQUIREMENTS** | |
| **1.** | General Guidance notes 1 - 6 shall be observed | |
| 1 | The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.<br>This shall include: | If the manufacturer follows this standard in his design and manufacturing process, this European Standard gives a valuable set of technical requirements to assist in fulfilling this ER with regard to general [1] X-ray radiation-related aspects of the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons (refer to Clauses 4 to 13 of this collateral standard). |
| | - reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and | This European Standard provides requirements to minimize risks of use error for the following aspects:<br>201.12.4.101 Operating modes<br>201.7.9.2.101 (Instructions for use) w) About function<br>201.7.9.3.101 (Technical Description) a) controlled access area |
| | - consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users). | Covered only with respect to 201.7.9.2.101 (Instructions for Use) p) Recommended training: Only to be used by professional and licensed users. |
| **2.** | General Guidance notes 1 - 6 shall be observed | |
| 2 | The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.<br><br>In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: | 1st paragraph covered under the condition that 2nd paragraph (including the following 3 bullets) is taken into account.<br>2nd paragraph, including the following 3 bullets, are covered for hazardous outputs inherent to MR equipment, under the condition that<br>- the manufacturer implements state of the art risk controls as reflected in 201.4, to 201.17, 202<br>- and EN ISO 14971 (2012) including its Annex ZA. |



1) This standard is intended to provide a set of general specifications to be complemented by existing particular/device specific standards, or by other means, such as risk management.

| No. | Essential Requirements | Coverage of EN 60601-2-33 |
|---|---|---|
| | - eliminate or reduce risks as far as possible (inherently safe design and construction), | |
| | - where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, | |
| | - inform users of the residual risks due to any shortcomings of the protection measures adopted. | |
| 3 | The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer. | MR equipment following the design rules set out by this European Standard is intended for medical diagnosis, as called out in Article 1 (2) (a). |
| 4 | The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use. | Covered in respect to Quality Assurance and Planned Maintenance, see<br>201.7.9.2.101 Instructions for Use<br>q) quality assurance<br>r) maintenance |
| **5.** | General Guidance notes 1 - 6 shall be observed | |
| 5 | The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer. | No specific requirements in this standard. |
| **6.** | General Guidance notes 1 - 6 shall be observed | |
| 6 | Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended. | Covered for hazardous outputs inherent to MR equipment, see<br>a) for physiologic effects due to electromagnetic field exposures:<br>201.12.4 Protection against hazardous output<br>b) for acoustic noise:<br>201.9.6.2.1 Audible acoustic energy<br>201.7.9.2.101 d) Exposure to excessive acoustic noise |
| **II.** | **REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION** | |
| General Guidance notes 1 - 6 shall be observed | | |
| 7 | **Chemical, physical and biological properties** | |
| 7.1 | The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I (3) on the 'General requirements'.<br><br>Particular attention must be paid to: | Covered for the certain particular device characteristics of MR Equipment (see below) |

| No. | Essential Requirements | Coverage of EN 60601-2-33 |
|---|---|---|
| | - the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, | No specific requirements in this standard. |
| | - the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device, | Not applicable for MR Equipment (per its intended use) |
| | - where appropriate, the results of biophysical or modeling research whose validity has been demonstrated beforehand. | Not applicable for MR Equipment |
| 7.2 | The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of the exposure. | No specific requirements in this standard. |
| 7.3 | The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; | No specific requirements in this standard. |
| | if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use. | Not applicable for MR Equipment |
| 7.4 | Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC. | Not applicable for MR Equipment |
| | For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. | Not applicable for MR Equipment |

| No. | Essential Requirements | Coverage of EN 60601-2-33 |
|---|---|---|
| | Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.<br>Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device.<br>When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure. | |
| 7.5 | The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. | Covered with respect to accidental Helium losses:<br>201.7.9.3.101 (Technical Description)<br>c) safety provisions in the event of a quench, and<br>201.7.9.2.101 (Instructions for Use)<br>f) Liquid and gaseous cryogens |
| | Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances. | Not applicable for MR Equipment |

| No. | Essential Requirements | Coverage of EN 60601-2-33 |
|---|---|---|
| | If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labeled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates. | Not applicable for MR Equipment |
| | If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures. | Not applicable for MR Equipment |
| 7.6 | Devices must be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used. | No specific requirements in this standard. |
| 8 | **Infection and microbial contamination** | General Guidance note 2 and 3 shall be observed |
| 8.1 | The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use. | No specific requirements in this standard. |
| 8.2 | Tissues of animal origin must originate from animals that have been subject to veterinary controls and surveillance adapted to the intended use of the tissues. | Not applicable for MR Equipment |
| | Notified Bodies shall retain information on the geographical origin of the animals. | Not applicable for MR Equipment |
| | Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other *transmissible* agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process. | Not applicable for MR Equipment |
| 8.3 | Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened. | Not applicable for MR Equipment |