SLOVENSKI STANDARD
SIST EN 60601-2-66:2016

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Nadomešča:
SIST EN 60601-2-66:2013

Medicinska električna oprema - 2-66. del: Posebne zahteve za osnovno varnost in bistvene lastnosti slušnih pripomočkov in sistemov slušnih instrumentov

Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems

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Ta slovenski standard je istoveten z: EN 60601-2-66:2015

ICS:

11.180.15	Pripomočki za gluhe osebe in osebe z okvaro sluha	Aids for deaf and hearing impaired people

SIST EN 60601-2-66:2016 **en**

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

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-66

November 2015

ICS 11.180.15; 17.140.50

Supersedes EN 60601-2-66:2013

English Version

Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems (IEC 60601-2-66:2015)

Appareils électromédicaux - Partie 2-66: Exigences particulières pour la sécurité de base et les performances essentielles des instruments d'audition et systèmes d'audition
(IEC 60601-2-66:2015)

Medizinische elektrische Geräte - Teil 2-66: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Hörgeräten und Hörgerätesystemen
(IEC 60601-2-66:2015)

This European Standard was approved by CENELEC on 2015-07-31. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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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

The text of document 29/851/FDIS, future edition 2 of IEC 60601-2-66, prepared by IEC/TC 29 "Electroacoustics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-66:2015.

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)	2016-05-27
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-07-31

This document supersedes EN 60601-2-66:2013.

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.

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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.

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Endorsement notice

The text of the International Standard IEC 60601-2-66:2015 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 60118-4:2014	NOTE	Harmonized as EN 60118-4:2015 (not modified).
IEC 60318-5:2006	NOTE	Harmonized as EN 60318-5:2006 (not modified).
IEC 60601-1-4:1996	NOTE	Harmonized as EN 60601-1-4:1996 (not modified).
IEC 60601-1-9	NOTE	Harmonized as EN 60601-1-9.
IEC 60601-1-10	NOTE	Harmonized as EN 60601-1-10.
IEC 60645-1:2012	NOTE	Harmonized as EN 60645-1:2015 (not modified).
IEC 62489-1:2010	NOTE	Harmonized as EN 62489-1:2010 (not modified).
ISO 80000-8:2007	NOTE	Harmonized as EN ISO 80000-8:2007 (not modified).

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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.

NOTE 1 When 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.

Annex ZA of EN 60601-1:2006 applies except as follows:

Publication	Year	Title	EN/HD	Year
Replacement:				
IEC 60950-1	2005	Information technology equipment - Safety - Part 1: General requirements	EN 60950-1	2006
(mod)			+AC	2011
			+A11	2009
+A1 (mod)	2009		+A1	2010
			+A12	2011
+A2 (mod)	2013		+A2	2013
Addition:				
IEC 60118-0	2015	Electroacoustics - Hearing aids - Part 0: Measurement of the performance characteristics of hearing aids	EN 60118-0	2015
IEC 60118-13	-	Electroacoustics - Hearing aids - Part 13: Electromagnetic compatibility (EMC)	EN 60118-13	-
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
			+ corr. March	2010
+A1	2012		+A1	2013
			+A1/AC	2014
			+A12	2014

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Publication	Year	Title	EN/HD	Year
IEC 60601-1-11	2015	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	EN 60601-1-11	2015
IEC 62304	-	Medical device software - Software life-cycle processes	EN 62304	-
IEC 62366	2007	Medical devices - Application of usability engineering to medical devices	EN 62366	2008

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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 the EU Directives 93/42/EEC as amended by 2007/47/EC.

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 This standard is intended to be applied in its entirety only. Selected clauses or subclauses may be not applicable due to the specific type of equipment under consideration. It is necessary to understand and apply Clauses 1 to 5. It is also recommended to understand and apply those clauses which contain general requirements related to a specific subclause. Elements of the standard that are not cited in Table ZZ.1 may be relevant for the appropriate fulfilment of certain essential requirements through indirect reference, and for safety and performance aspects of the device, that are not addressed through essential requirements.

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NOTE 2 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 to the MDD (Directive 93/42/EEC amended by 2007/47/EC). 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.

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NOTE 3 With respect to Note 4 of 4.2.2 General requirement for risk management, 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 4 References in the Clauses 3 to 17 or in the Annexes of this standard specify whether the normative references listed in Clause 2 as cited in Annex ZA are to be applied in whole or in part.

NOTE 5 This Annex ZZ is based on Normative References according to Annex ZA, replacing the references in the core text.

NOTE 6 According to the scope of this standard the coverage in Table ZZ.1 only applies to the design and construction of HEARING INSTRUMENTS or HEARING INSTRUMENT SYSTEMS. This European Standard lists in Table ZZ.1 only the essential requirements covered.

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

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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 60601-2-66
I.	**GENERAL REQUIREMENTS**	
1	General Guidance note 2 and 3 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. This shall include:	The application of EN 60601-2-66 and the documents referenced in there (below referenced as “this document” or “this standard”) support a manufacturer to design HEARING INSTRUMENTS and HEARING INSTRUMENT SYSTEMS (below “devices”) 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, while accepting only risks associated with their intended use that constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. Details and exclusions supporting this general statement follow in order of the essential requirements below. Where the intended use of devices exceeds the scope of this document, the manufacturer may need to apply additional methods to achieve conformity to the essential requirements. Manufacturing aspects are not covered by this document! This statement applies to several essential requirements below but will not be repeated at each line, in order to provide for a better usability of this document.
	– 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	The application of this document (201.7.1.1, 201.12.2 with reference to EN 62366) reduces, 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.

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No.	Essential Requirements	Coverage of EN 60601-2-66
	– 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).	This document (201.7.9.1, 201.7.9.2.2) puts 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).
2	General Guidance note 2 and 3 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. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:	The requirements of this document for the design and construction of the devices conform to safety principles, taking account of the generally acknowledged state of the art at the time it has been released (2014). This document references EN ISO 14971, the application of which (4.3) does provide for the coverage of potential developments and new conclusions in hearing aid safety that became known after the release of this particular standard. The requirements of this document have been established by selecting the most appropriate solutions to the particular devices and their risks, by applying the following principles in the following order:
	– 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 <u>performances</u> 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.	The <u>performance</u> aspect (clinical evaluation) is not covered by this document unless basic safety is concerned. HEARING INSTRUMENTS do not have ESSENTIAL PERFORMANCE (201.4.3). If a manufacturer extends the intended use to safety critical functional claims, the resulting ESSENTIAL PERFORMANCE is not covered by application of this particular standard.

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No.	Essential Requirements	Coverage of EN 60601-2-66
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.	A failure of characteristics of HEARING INSTRUMENTS could not affect the clinical conditions and safety of the patients and other persons (201.4.3). If a manufacturer extends the intended use to safety critical functional claims, the resulting ESSENTIAL PERFORMANCE is not covered by application of this particular standard.
5	General Guidance note 2 and 3 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.	Covered by requirements to design and packaging (201.7.2.17) to withstand transport and storage with regards of mechanical strength (201.15.3), resistance to environmental conditions (201.15.3.7) and the necessary instructions (201.7.9.2.2).
6	General Guidance note 2 and 3 shall be observed	
6	Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.	The requirements of this document are sufficient to keep risks to an acceptable level when weighed against the performances intended. This document also references EN ISO 14971, the application of which requires the criteria for acceptable risks (3.2). In general, HEARING INSTRUMENTS do not have side-effects beyond convenience issues. The reduction of unintentional exposure to excessive acoustic noise is covered in 201.9.6 regarding the design, in 201.7 regarding correct application 201.13.1.2 in case of faults.
6a	Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.	The performance aspect (clinical evaluation) is not covered by this document unless basic safety is concerned.
II.	**REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION**	
7	**Chemical, physical and biological properties**	General Guidance note 2 and 3 shall be observed
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 on the 'General requirements'. Particular attention must be paid to:	See section I and the details in the three indents below.

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No.	Essential Requirements	Coverage of EN 60601-2-66
	– the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,	Covered in respect of the toxicity: 11.7 Biocompatibility, the manufacturer should apply the appropriate part of the EN ISO 10993 series. Flammability: Risks of fire and high temperatures covered in 201.11.1.1, 201.13.1.2.
	– the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device,	Covered in respect of the biocompatibility: 11.7 the manufacturer should apply the appropriate part of the EN ISO 10993 series.
	– where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.	Such modelling research is not applicable to HEARING INSTRUMENTS.
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 exposure.	Covered in respect of the biocompatibility: 11.7 the manufacturer should apply the appropriate part of the EN ISO 10993 series.
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;	This document covers (201.15.3.7, 201.11.6.6) the design of devices 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. The requirements for HEARING INSTRUMENTS that are intended to be used in explosive and oxygen-enriched atmospheres are not contained in this standard (201.11.2).
	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.	HEARING INSTRUMENTS are not intended to administer medicinal products.
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 to HEARING INSTRUMENTS.

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No.	Essential Requirements	Coverage of EN 60601-2-66
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 by a warning in 201.7.9.2.4.
	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 labelling of dangerous substances.	HEARING INSTRUMENTS do not contain such substances.
	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 labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates.	HEARING INSTRUMENTS are not intended to administer medicinal products.
	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.	HEARING INSTRUMENTS are not intended to administer medicinal products.
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.	Covered in 201.11.6.5
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.	Design covered in 201.12.2, 201.11.6.6 and instruction covered in 201.7.9.2.12.
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 to HEARING INSTRUMENTS.
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 to HEARING INSTRUMENTS.

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No.	Essential Requirements	Coverage of EN 60601-2-66
8.4	Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	Not applicable to HEARING INSTRUMENTS.
8.5	Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.	Not applicable to HEARING INSTRUMENTS.
8.6	Packaging system for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination;	Aspects of packaging not covered.
	the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.	Not applicable to HEARING INSTRUMENTS.
8.7	The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.	Not applicable to HEARING INSTRUMENTS.
9	**Construction and environmental properties**	General Guidance note 2 and 3 shall be observed
9.1	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices.	Covered by 201.5.5, 201.7.9.2.5, 201.6.2, 201.7.9.2.9, 201.8.1, 201.8.2.1 and 201.8.4.2 as well as the required application of risk and usability management 4.2, 201.7.1.1, 201.12.2.
	Any restrictions on use must be indicated on the label or in the instructions for use.	Covered by 201.7.9.2, 201.7.9.2.2 and 201.7.9.3.1.
9.2	Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible:	
	– the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;	There are no risks of injury, in connection with the physical features, including the volume/pressure ratio, dimensional and ergonomic features of HEARING INSTRUMENTS. Mechanical risks are covered by 201.9.

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No.	Essential Requirements	Coverage of EN 60601-2-66
	– risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration;	The reference to EN 60118-13 in 201.17 of this document provides design and test requirements with regards to magnetic fields, external electrical influences, electrostatic discharges which are suitable to remove or minimize as far as possible risks to hearing aids. 201.5.3, 201.5.7, 201.7.2.17, 201.7.9.2.1, 201.7.9.2.2, 201.15.3.7 of this document provide design and test requirements with regards to climatic environmental conditions which are suitable to remove or minimize as far as possible risks to hearing aids from pressure, temperature or variations in pressure.
	– the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;	The reference to EN 60118-13 in 201.17 of this document provides design requirements to remove or minimize as far as possible risks connected with reciprocal interference by EMC phenomena with other devices. 201.7.9.2.2 contains requirements for warnings regarding other potential causes of reciprocal interference.
	– risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	HEARING INSTRUMENTS do not need calibration. Maintenance is possible. 201.15.2 contains requirements with regards to serviceability.
9.3	Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition.	Risks of fire and high temperatures covered in 201.11.1.1, 201.13.1.2 The requirements for HEARING INSTRUMENTS that are intended to be used in explosive and oxygen-enriched atmospheres are not covered in this document.
	Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.	HEARING INSTRUMENTS are normally not exposed to flammable substances or to substances which could cause combustion. The requirements for HEARING INSTRUMENTS that are intended to be used in explosive and oxygen-enriched atmospheres are not covered in this document.

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No.	Essential Requirements	Coverage of EN 60601-2-66
10	**Devices with a measuring function**	
10.1	Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device.	Not applicable to HEARING INSTRUMENTS.
	The limits of accuracy must be indicated by the manufacturer.	Not applicable to HEARING INSTRUMENTS.
10.2	The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.	Not applicable to HEARING INSTRUMENTS.
10.3	The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC.	Not applicable to HEARING INSTRUMENTS.
11	**Protection against radiation**	General Guidance note 2 and 3 shall be observed
11.1	General	
11.1.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	Not applicable to HEARING INSTRUMENTS.
11.2	Intended radiation	
11.2.1	Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.	Not applicable to HEARING INSTRUMENTS.
11.2.2	Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	Not applicable to HEARING INSTRUMENTS.
11.3	Unintended radiation	
11.3.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.	Covered with respect to electromagnetic compatibility in 201.17 by the requirement to apply EN 60118-13 as well as applicable radio standards for wireless interfaces. The risks of tissue exposure to the emission of electromagnetic fields by wireless interfaces of HEARING INSTRUMENTS are not covered in this document.

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