

**STANDARD**  
**NORME EUROPEAN**  
**EUROPAISCHINE NORM**

**June 1998**

ICS

Descriptors: Hearing Aids, General Requirements, Medical Devices Directive. English version.

**General requirements for hearing aids:**  
**EUROPEAN HEARING INSTRUMENT MANUFACTURERS ASSOCIA-**  
**TION**

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## **Foreword**

This European Standard was prepared by the EHIMA Technical Committee after failure of CENELEC to produce a positive vote for the publication of the draft CENELEC Standard prEN 50220 "General requirements for hearing aids".

This standard is almost identical in many respects to prEN 50220 and has taken into account the comments raised during the voting that resulted in a negative vote for publication.

The main purpose of this standard, and prEN50220, is to provide manufacturers with a guide to **one** method of showing conformity with the Medical Devices Directive 93/42/EEC.

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## **1. Scope**

This European Standard specifies the general requirements for hearing aids and specifies the tolerances on measured electroacoustic performance characteristics, but does not give requirements for electroacoustic performance, in order to provide **one** method of showing conformity with the Medical Devices Directive 93/42/EEC. A guide to the classification of hearing aids and the relevant clauses of the Essential Requirements of the Medical Devices Directive are given in Annex Z.

General requirements include a minimum set of performance data and the method of measurement, electrical safety, electromagnetic compatibility, biological effects of materials used, labeling, marking and user instruction.

The measurement requirements of series EN 60118 and HD 450 (IEC 118-series) are referenced, as appropriate.

The following types of hearing aids are not covered by this standard:

- Cochlear implants
- Other implanted hearing aids
- Bone conduction hearing aids
- Educational hearing aids (i.e. group hearing aids, auditory trainers etc.)

Where a measurement of hearing level is undertaken through the hearing aid then those functions necessary for that measurement are not covered by this standard and should meet the requirements of IEC 60645-1.

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## 2. Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 60 118-0	Hearing aids Part 0: Measurement of electroacoustical characteristics
EN 60 118-1	Hearing aids Part 1: Hearing aids with induction pick-up coil input
EN 60 118-2	Hearing aids Part 2: Hearing aids with automatic gain control circuits
HD 450.6	Hearing aids Part 6: Characteristics of electrical input circuits
IED 60118-13	Hearing aids Part 13: Electromagnetic compatibility (EMC)
EN 60065	Safety requirements for mains operated electronic and related apparatus for household and similar general use - Group Safety Publication
EN 60601-1-1	Medical electrical equipment Part 1: General requirements for safety - 1. Collateral standard: Safety requirements for medical electrical systems
EN 30 993-1	Biological evaluation of medical devices Part 1: Evaluation and testing
IEC 60645-1 prEN 1441*	Audiometers Part 1: Pure-tone audiometers Medical devices. Risk analysis
IEC 60711	Occluded-ear simulator for the measurement of earphones coupled to the ear by ear inserts
ISO Information Publication ISBN 92-67- 10188-9	Guide to the expression of uncertainty in measurement

\* prEN 1441:1994 - When the document has been finalised as EN 1441, it applies

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## 3. Definitions

For the purpose of this standard the following definitions apply in addition to those given in series EN 60118 and HD 450. Measurements may be made in either the IEC 60126: 1973 acoustic coupler or the IEC 60711: 1981 occluded ear simulator provided that the device is clearly stated.

3.1 Maximum full-on acoustic gain: The highest full-on acoustic gain value, when measured over the entire frequency range as specified in clause 7 of EN 60118-0:1993.

3.2 Maximum OSPL90: The highest OSPL90 value, over the frequency range, as specified in clause 7 of EN 60118-0:1993.

3.3 Custom-made hearing aid: A hearing aid where the electroacoustic parts are placed in a shell or outer casing made from an impression of the individual user's ear.

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## 4. General requirements

### 4.1 General

Hearing aids shall, when transported, stored, operated in normal use, and maintained according to the instructions of the manufacturers, cause no safety hazard which could reasonably be foreseen and which is not connected with its intended application, in normal condition and in single fault condition.

### 4.2 Tolerances on specified performance

The tolerances required on the performance characteristics of the hearing aid are given in table 1 and are the basis for evaluating the manufacturer's claimed performance. The manufacturer shall, as applicable, state a tolerance/maximum value for items e) and g) to l) in 4.4. of this standard.

Hearing aids are designed to meet the individual requirements of hearing impaired people and consequently the electroacoustic performance of hearing aids varies with the need of the user, this need is met by a large range of types and models of hearing aid. It is therefore not appropriate to specify standardised values for electroacoustic performance, therefore this standard only specifies the tolerances on the performance as stated by the manufacturer.

All hearing aids placed on the market shall meet the requirements stated in Table 1.

### 4.3 Interpretation of tolerances

The tolerances in table 1 apply to the performance of the hearing aid as determined with an infinitely small measurement of uncertainty. To ensure that performance is within a specified tolerance taking into account the limited accuracy of any measurement, the tolerance on the measured value must be less than the specified tolerance by the expanded uncertainty ( $k=2$ ) of measurement.

To ensure that performance is outside the specified tolerance according to the "Guide to the Expression of Uncertainty in Measurement", the tolerance on the measured value must be greater than the specified tolerance by the expanded uncertainty ( $k=2$ ) of measurement.\*

\*As an example, suppose that the expanded uncertainty ( $k=2$ ) for the measurement of the coupler sound pressure level is 1.5dB. The OSPL90 would have to be within 2.5 dB of the specified value to ensure that 4 dB was being achieved. When checking, however, an aid for non-compliance

of the parameter, using a test equipment with an uncertainty no better than 1.5 dB, the measured value would have to exceed 5.5 dB.

#### 4.4 Specified data of the hearing aid

The technical data of the hearing aid shall contain the information according to table 1, as applicable.

A description of any special performance characteristics shall be given in addition to those stated in table 1. Any specific mechanical and other properties of the aid, including the layout of any user or preset controls, shall be provided by the manufacturer. Illustrations and explanations shall be attached as applicable.

The operation and setting of each control or programmable parameter to be adjusted by a dispenser or user shall be explained and stated by the manufacturer. The battery types, earphones, cords, connectors, tubing and accessories required to achieve the indicated performance shall be stated.

**Table 1: Technical Data**

Item	Characteristic	Presentation	Tolerance max. value	Test Condition	Reference
a)	Reference test frequency	value in Hz			4.16 of EN 60118-0:1993
b)	OSPL90	value in dB SPL	+/- 4 db**	At reference test frequency	7.2 of EN 60118-0:1993
c)	Maximum OSPL90	value in dB SPL	+/- 4 db**		7.2 of EN 60118-0:1993
d)	Full-on gain	value in B	+/- 5 db**	At reference test frequency	7.3 of EN 60118-0:1993
e)	Maximum full-on acoustic gain	value in dB	+/- 5 db**		7.3 of EN 60118-0:1993
f)	Reference test gain	value in dB		At reference test frequency	4.18 of EN 60118-0:1993
g)*	Total harmonic distortion at 500,800 and 1600 Hz	value in %	shall be stated by the manufacturer	70 dB input	7.12.1 of EN 60118-0:1993
h)*	Equivalent input noise level	value in dB SPL	typical and maximum value shall be stated by the manufacturer		7.14.1 of EN 60118-0:1993
i)*	Battery Current	value in mA	typical and maximum value shall be stated by the manufacturer		7.11 of EN 60118-0:1993
j)*	Max. sensitivity level with induction pick up coil	value in dB	typical and maximum value shall be stated by	At reference test frequency	5.6 of EN 60118-1:1995

			the manufacturer		
k)*	Total harmonic distortion with induction pick up coil input at 500,800 and 1600 Hz	value in %	shall be stated by the manufacturer	100 mA/m	5.8 of EN 60118-1: 1995
l)*	Sensitivity of electrical input	value in mV	shall be stated by the manufacturer		HD 450.6 S1: 1986
m)	OSPL90 frequency response	curve in dB SPL	+ - 4dB SPL**	500 to 3.000 Hz	7.2 of EN 60118-0: 1993
n)	Basic frequency response	curve	+ - 4dB** + - 6dB**	200 to 2.000 Hz 2.000 to 4.000 Hz	7.4 of EN 60118-0: 1993
o)*	Effect of controls	curves	Manufacturer to specify min/max range	Manufacturer to show appropriate curves	EN 60118-0: 1993 and EN 60118-2: 1995
p)	Basic frequency response with induction pick up coil	curve	+ - 6dB**	500 to 3.000 Hz	5.4 of EN 60118-1: 1995

\* Due to the specific nature of the measurement, it is not possible to assign tolerances and values to cover all hearing aids

\*\* Relative to the reference value/response stated by the manufacturer

#### 4.5 EMC

If radio frequency transmissions are used they shall meet the requirements of the relevant standards.

Measurements and evaluation of hearing aids shall be made in accordance with IEC 60118-13.

## 5. Safety requirements

The manufacturer shall establish a risk analysis, for example in accordance with EN 1441:1998, in order to show that the aid is 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 risk which may be associated with their 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.

### 5.1 Biological effects

Documentation for the biological compatibility of the materials used shall be provided by the manufacturer. If tests are required they should be performed according to EN 30993-1.

### 5.2 Electrical connections to the hearing aid

Where the hearing aid has means for the connection to other devices, the safety of the devices to which a hearing aid is connected, shall conform with EN 60601-1-1 or EN 60665, as appropriate.

### 5.3 Batteries for hearing aids

The battery drawer shall comply with the requirements of EN 60086-1 and shall be designed to prevent reversal of battery insertion.

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## **6 Labelling Requirements**

### **6.1 Permanent marking on hearing aid**

Permanent marking on hearing aids shall be:

- a) Name of the manufacturer
- b) Serial Number
- c) Model of hearing aid. If this is not possible (custom-made hearing aids/devices) documents accompanying the hearing aid/device shall state the model.
- d) For hearing aids/devices designed to be used on one side of the head an identification for the left or right side.
- e) A "+" symbol to indicate the positive connection for the battery insertion.

Note. CE marking for the hearing aids is not required on the hearing aid itself due to the small size of the instrument. The CE mark is required on the instruction leaflet.

### **6.2 Instructions for use**

The user Instructional brochure accompanying each hearing aid shall contain the following information and instructions for use, to the extent applicable to the particular requirements and characteristics of the hearing aid. Instructions for use shall include information about the purpose and intended use of the hearing aid.

- a) An illustration(s) of the hearing aid indicating operating controls, user adjustments, and battery compartments.
- b) Information on the function of all controls intended for user adjustment.
- c) A description of any accessory that may accompany the hearing aid.
- d) Specific instruction for:
  - d1) Use of the hearing aid
  - d2) Maintenance and care of the hearing aid, including the procedure to follow in washing the earmould, when replacing tubing on those hearing aids that use tubing, and in storing the hearing aid when it will not be used for an extended period of time.
  - d3) Replacing or recharging the batteries, including a generic designation of replacement batteries.
- e) Information on how and where to obtain repair service, including at least one specific address where the user can go, or send the hearing aid to, to obtain such repair service.
- f) A description of commonly occurring avoidable conditions that could adversely affect or damage the hearing aid, such as dropping, immersing, strong electromagnetic fields or exposing the hearing aid to excessive heat.
- g) Identification of any known side effects associated with the use of a hearing aid that may warrant consultation with a physician, e.g. skin irritation and accelerated accumulation of cerumen (ear wax).
- h) Warning: external devices connected to the electrical input must be safe according the requirements of EN 60601-1-1 or EN 60065, as appropriate.

i) Warning: risk of hearing aids worn in mines or other explosive areas, unless certified for such use

### 6.3 Technical Data

A technical data sheet shall be available for the dispenser or fitter of the hearing aid/device. The tolerances on the technical data shall meet the requirements of clause 4 of this standard.

For custom-made hearing aids an individual sheet shall accompany each hearing aid.

### 6.4 Warnings

The instructional brochure shall contain the following warning statement: (This provision is required only for those hearing aids with a maximum sound pressure level capability greater than 132 dB).

"WARNING TO HEARING AID DISPENSERS: Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels, as measured with an IEC 60711: 1981 occluded ear simulator, because there may be a risk of impairing the remaining hearing of the hearing aid user."

## Annex Z (informative)

**Part Z1** of this Annex indicates the likely classification of hearing aids for the purposes of the Medical Devices Directive.

**Part Z2** indicates the clauses of the Essential Requirements of the Medical; Devices Directive that are likely to be applicable.

WARNING: Other requirements and other EC Directives can be applicable to the product falling within the scope of this standard.

Compliance with this standard provides one means of conforming with the specific essential requirements of the Directive concerned.

### Part Z1 Interpretation of the classification of hearing devices according to the Medical Devices Directive.

Device	Classification	CE - mark according to MDD ?	Comments
Acoustical tubing (for earmoulds)	Custom	No	Tubing may affect the acoustical properties of earmoulds, and hence the hearing aids. Tubing is part of a custom earmould, and classified accordingly.
ALD (assistive listening device)	-	No	Examples are FM equipment, IR equipment, teleloop systems, radio, TV. ALDs are accessories, but not medical devices, since they are also used for other purposes.
Audio Shoe	-	No	If the audio shoe can be removed from the hearing aid, and the hearing aid still works as intended by the manufacturer, the audio shoe is not an integral part of the hearing aid. It is therefore defined as an accessory, but is - in

			analogy to a cord or an ALD - not a medical device. <b>Note:</b> Products which are to be connected to the audio shoe must comply with IEC 6065 or IEC 60601-1, and this must be stated in the labelling.
Battery (primary cell)	-	No	An accessory, but not a medical device, since it is also used for other purposes
Battery (rechargeable)	-	No	An accessory, but not a medical device, since it is also used for other purposes
Battery tester	-	No	An accessory, but not a medical device, since it is also used for other purposes
Bone Conductor	IIa	Yes	A bone conductor directly affects the output of hearing aids, and is therefore classified as IIa. They are also sold separate from the hearing aid, and must therefore be CE marked
Behind-the-ear (BTE) hearing aids	IIa	Yes	BTE hearing aids are classified as IIa
BTE kit	IIa	Yes	BTE kits may be CE-marked, provided they subsequently are assembled according to the manufacturers instruction
Body-worn hearing aids (BW)	IIa	Yes	BW hearing aids are classified as IIa.
Charger (for rechargeable batteries)	-	No	An accessory, but not a medical device, since it is also used for other purposes
Cleaning fluid (to clean hearing aids/earmoulds by the user)	I	Yes	Cleaning fluid is a medical device, but only if specifically developed to clean hearing aids etc.
Cord	-	No	If the cord can be removed from the hearing aid, and the hearing aid still works as intended by the manufacturer, the cord is not an integral part of the hearing aid. It is therefore defined as an accessory, but is - since it may be used for other purposes - not a medical device. <b>Note:</b> Products which are to be connected to the cord must comply with IEC 6065 or IEC 60601-1, and this must be stated in the labelling
CROS unit	IIa	No	An option, and hence an integral part of the hearing aid
Dummy hearing aid	-	No	Not functional, and therefore not a medical device
Earmould	Custom	No	An earmould is an accessory that can affect safety. Cust-

(custom-made)			om-made earmoulds cannot be CE-marked, but must comply with the MDD, Annex VIII
Earmould (standard)	IIa	Yes	An earmould is an accessory that can affect safety
Earphone	IIa	Yes	An earphone directly affects the output of hearing aids, and is therefore classified as IIa. It is also sold separate from the hearing aid, and must therefore be CE-marked
Eyeglass hearing aid (EG)	IIa	Yes	Eyeglass hearing aids are classified as IIa
Eyeglass adaptor	IIa	No	An option, and hence an integral part of the hearing aid
Hook	IIa	No	An option, and hence an integral part of the hearing aid
Impression material	I	Yes	A substance that, although for temporary use, may have health and safety implications. Hence classified as I
In-the-ear (ITE) hearing aid	IIa	Yes	ITE hearing aids are classified as IIa
ITE assembly	Custom	No	If an operator assembles ITEs deviating from an approved manufacturers instructions, such aids are classified as custom devices, cannot be CE-marked, but must comply with MDD, Annex VIII
ITE kit	IIa	Yes	ITE hearing aids are classified as IIa. They may be ear-marked, provided the assembler adheres to the manufacturers instructions
Maintenance tool	-	No	An accessory, but not a medical device, since it is also used for other purposes
PC (for programming)	-	No	An accessory, but not a medical device, since it is also used for other purposes
Programming interface	I	Yes	A medical device which is only temporarily connected to the hearing aid, and hence classified as I
Programming unit	-	No	A hand-held device, operationally equivalent to a screwdriver, and therefore not a medical device
Remote control (integral)	IIa	Yes	An integral remote control is an essential part of the hearing aid, since the aid will not function without. Nevertheless it may be sold separately, and must therefore be independently CE-marked
Remote control (optional)	I	Yes	An optional remote control is an accessory that is sold separately, but is intended to control the hearing aid parameters in use. It is therefore classified as I
Remote microphone	-	No	An accessory, but not a medical device, since it is also used for other purposes

Repair tool	-	No	Repair tools are not medical devices, since they are also used for other purposes
Software (fitting)	-	No	PC-based software for hearing aid fitting is operationally equivalent to a description of produce properties, and hence not a medical device
Software (integrated)	IIa	No	An integral part of the hearing aid
Spare part	-	No	Spare parts for service/repair are not medical devices
Tameper-proof battery cover	IIa	No	An option, and hence an integral part of the hearing aid
Volume control cover	IIa	No	An option, and hence an integral part of the hearing aid
Wax filter	IIa	No	An option, and hence an integral part of the hearing aid

**Part Z2. Indication of the clauses of the Essential Requirements of the Medical Devices Directives that are likely to be applicable.**

**Note: Where there is an indication of "None" in the reference column, no specific standards are available. References are to clauses in this standard unless otherwise stated.**

<b>ESSENTIAL REQUIREMENTS</b>				
<b>According to annex 1 of the Medical Devices Directive (93/42/EEC)</b>				
<b>EU no.</b>	<b>Ref. no.</b>	<b>1. GENERAL REQUIREMENTS</b>	<b>COMMENTS</b>	<b>REFERENCES</b>
1	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 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	Applicable. In general the health and safety risks associated to hearing aids use are minimal, compared to the benefits derived, but still have to be assessed	Clause 5
2	2	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking into account the generally acknowledged state of the art <b>In selecting the most appropriate solutions the manufacturer must apply the following principles in the following order:</b>	Applicable	Clause 5

	2.1	eliminate or reduce risks as far as possible (inherently safe design and construction)	Applicable	Clause 5
	2.2	where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated	Applicable	Clause 5
	2.3	inform users of the residual risks due to any shortcomings of the protection measures adopted	Applicable	Clause 5
3	3	The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packed 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 hearing aids is intended for alleviation of handicap (ref. Article 1(2)(a))	Table 1 and Clause 4.4
4	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	The hearing aid may be adversely affected by environmental conditions, but even failure will not constitute a safety hazard to the patient's hearing	Clause 5
5	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	Applicable	Clause 4
6	6	Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended	Applicable. Medical opinion, based on experience over many years, has indicated that hearing aids provide a level of performance vastly superior to the minimal side effects encountered	Clause 4
<b>7</b>	<b>7</b>	<b>Chemical physical and biological properties</b>		
7.1	7.1	The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section 1 on 'General requirements'	Applicable	Clause 5
		<b>Particular attention must be paid to:</b>		

	7.1.1	the choice of materials used particularly as regards toxicity and where appropriate flammability	Applicable	Clause 5
	7.1.2	the compatibility between the materials used and biological tissues, cells and body fluids, taking into account the intended purpose of the device	Applicable	Clause 5
7.2	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 into account the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure	Not applicable since hearing aids are passive devices during transport, and only become active when a battery is inserted	
7.3	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; 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 since hearing aids are not intended to be used with any materials, substances or gases, not intended to administer medicinal products	
7.4	7.4	Where device incorporates, as an integral part, a substance which if used separately may considered be medicinal product defined in Article 1 of Directive 65/65/65/EEC and which is liable to act upon the body with action ancillary to that of the device the safety quality and usefulness of the substance must be verified, taking into account the intended purpose of the device, by analogy with the appropriate methods specified in Directive 75/318/EEC	Not applicable, since no medicinal product or substance is incorporated in hearing aids	
7.5	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.	Not applicable. the only conceivable leaking substance would be minute amounts of KOH from zinc-air batteries, and no adverse health effects have ever been reported	
7.6	7.6	Devices must be designed and manufactured in	Not applicable, since	

		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.	worst-case risk implies that the hearing aid stops functioning, and therefore this is not likely to constitute a safety risk	
<b>8</b>	<b>8</b>	<b>Infection and microbial contamination</b>		
8.1	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.	Applicable	Clause 5
8.2	8.2	Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues.  Notified bodies shall retain information on the geographical origin of the animals.  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 transferable agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	Not applicable, since no materials of animal origin are incorporated in hearing aids	
8.3	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, since hearing aids are not sterile devices	
8.4	8.4	Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate validated method.	Not applicable, since hearing aids are not sterile devices	
8.5	8.5	Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.	Not applicable, since hearing aids are not sterile devices	
8.6	8.6	Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices	Not applicable, since hearing aids are not ste-	

		are to be sterilized prior to use minimize the risk of microbial contamination: the packaging system must be suitable taking into account the method of sterilization indicated by the manufacturer.	sterile devices	
8.7	8.7	The packaging and/or labelling of the device must distinguish between identical or similar Products sold in both sterile and non-sterile condition.	Not applicable, since hearing aids are not sterile devices	
<b>9</b>	<b>9</b>	<b>Construction and environmental properties</b>		
9.1	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. Any restrictions on use must be indicated on the label or in the instructions for use.	Applicable if electrical input is provided for	Clause 5.2
<b>9.2</b>	<b>9.2</b>	<b>Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible:</b>		
	9.2.1	the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features,	Applicable	Clause 5
	9.2.2	risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,	Applicable	Clause 5
	9.2.3	the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given,	Not applicable, since hearing aids do not generate any significant relevant emissions	
	9.2.4	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	Not applicable, since maintenance and calibration is always feasible	
9.3	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. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion	Applicable, however since the power source in hearing aids has insufficient energy to cause fire or explosion in normal conditions of use this is only applicable in certain cir-	See Clause 6.2(i)

			cumstances	
<b>10</b>	<b>10</b>	<b>Devices with measuring function</b>		
10.1	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. The limits of accuracy must be indicated by the manufacturer	Not applicable, since hearing aids perform no measuring function	
10.2	10.2	The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking into account the intended purpose of the device	Not applicable, since hearing aids perform no measuring function	
10.3	10.3	The measurements made by devices with a measuring function must be expressed in legal units confirming to the provisions of Council Directive 80/181/EEC* *OJ No L 39, 15.2. 1980, p. 40. Directive as last amended by directive 89/617/EEC (OJ no L 357, 7.12 1989, p. 28).	Not applicable, since hearing aids perform no measuring function	
<b>11</b>	<b>11</b>	<b>Protection against radiation</b>		
<b>11.1</b>	<b>11.1</b>	<b>General</b>		
11.1.1	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, since hearing aids emit no hazardous radiation	
<b>11.2</b>	<b>11.2</b>	<b>Intended radiation</b>		
11.2.1	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, since hearing aids emits no hazardous radiation.	
11.2.2	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, since hearing aids emits no hazardous radiation.	
<b>11.3</b>	<b>11.3.</b>	<b>Unintended radiation</b>		

11.3.1	11.3.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emissions of unintended, stray or scattered radiation is reduced as far as possible	Not applicable, since hearing aids emits no hazardous radiation.	
<b>11.4</b>	<b>11.4</b>	<b>Instructions</b>		
11.4.1	11.4.1	The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.	Not applicable, since hearing aids emits no hazardous radiation.	
<b>11.5</b>	<b>11.5</b>	<b>Ionizing radiation</b>		
11.5.1	11.5.1	Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.	Not applicable, since hearing aids emits no hazardous radiation.	
11.5.2	11.5.2	Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.	Not applicable, since hearing aids emits no hazardous radiation.	
11.5.3	11.5.3	Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation.	Not applicable, since hearing aids emits no hazardous radiation.	
<b>12</b>	<b>12</b>	<b>Requirements for medical devices connected to or equipped with an energy source</b>		
12.1	12.1	Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.	Applicable for programmable hearing aids, with respect to MPO.	None
12.2	12.2	Devices where the safety of the patients depends on an internal power supply must be equipped with means of determining the state of	Not applicable, since a failure of the power supply (battery) will	

		the power supply.	not compromise patient safety	
12.3	12.3	Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.	Not applicable, since hearing aids do not depend on an external power supply.	
12.4	12.4	Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.	Not applicable, since hearing aids do not monitor clinical parameters.	
12.5	12.5	Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.	Applicable to hearing aids with transmission systems such as RF CROS aids. Note that some remote controls and communication between hearing aids, may need to be considered	Clause 4.5
<b>12.6</b>	<b>12.6</b>	<b>Protections against electrical risks</b>		
	12.6.1	Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.	Applicable if hearing aid provides for electrical input, or is programmed through a galvanic connection	Clause 5.2
<b>12.7</b>	<b>12.7</b>	<b>Protection against mechanical and thermal risks</b>		
12.7.1	12.7.1	Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.	Not applicable. Hearing aids are dimensionally stable, and contain no exposed moving parts	
12.7.2	12.7.2	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	Not applicable, since hearing aids other than bone-conduction aids generate no significant unintentional vibrations	
12.7.3	12.7.3	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the	Not applicable, since noise (i.e. sound) emission is part of a specified performance	

		specified performance.		
12.7.4	12.7.4	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks.	Not applicable, since hearing aids do not include such connections.	
12.7.5	12.7.5	Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	Not applicable, since hearing aids do not generate heat.	
<b>12.8</b>	<b>12.8</b>	<b>Protection against the risk posed to the patient by energy supplies or substances</b>		
12.8.1	12.8.1	Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.	Applicable. Note that any hearing aid with possible maximum output sound pressure level above 132 dB SPL requires a special warning notice.	Clause 4
12.8.2	12.8.2	Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger.  Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.	Applicable. Designers should take care that no likely fault in the aid would result in high sound pressure reaching the earphone to cause acoustic trauma	Clause 4
12.9	12.9	The function of the controls and indicators must be clearly specified on the devices.  Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.	Applicable	Clause 4.4
<b>13</b>	<b>13</b>	<b>Information supplied by the manufacturer</b>		
13.1	13.1	Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking into account the training and knowledge of the potential users.  This information comprises the details on the label and the data in the instructions for use.  As far as practicable and appropriate, the in-	Applicable	Clause 6.2

		<p>formation needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.</p> <p>Instructions for use must be included in the packaging for every devices. By way of exception, no such instructions for use are needed for device in Class I or IIa if they can be used safely - without any such instructions.</p>		
13.2	13.2	Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.	Applicable	Clause 6
<b>13.3</b>	<b>13.3</b>	<b>The label must bear the following particulars</b>		
13.3	13.3.1	(a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of either the person responsible referred to in Article 14(2) or of the authorized representative of the manufacturer established within the Community or of the importer established within the Community, as appropriate;	Applicable	None
	13.3.2	(b) the details strictly necessary for the user to identify the device and the contents of the packaging;	Applicable	None
	13.3.3	(c) where appropriate, the word 'STERILE';	Not applicable, since hearing aids are not sterile.	
	13.3.4	(d) where appropriate, the batch code, preceded by the word 'LOT', or the serial number;	Applicable	None
	13.3.5	(e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;	Not applicable, since hearing aids have unlimited shelf life	
	13.3.6	(f) where appropriate, an indication that the device is for single use;	Not applicable, since hearing aids can be reused.	

	13.3.7	(g) if the device is custom-made, the words 'custom-made device';	Applicable for custom ITE (In The Ear)	None
	13.3.8	(h) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations';	Applicable for experimental hearing aids, only intended for clinical trials	None
	13.3.9	(i) any special storage and/or handling conditions;	Applicable	None
	13.3.10	(j) any special operating instructions;	Applicable	None
	13.3.11	(k) any warnings and/or precautions to take;	Applicable	None
	13.3.12	(l) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number;	Not Applicable	
	13.3.13	(m) where applicable, method of sterilization.	Not applicable, since hearing aids are not sterile devices.	
13.4	13.4	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.	Not applicable, since the intended purpose is considered obvious	
13.5	13.5	Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	Not applicable, since detachable components are considered interchangeable.	
<b>13.6</b>	<b>13.6</b>	<b>Where appropriate, the instructions for use must contain the following particulars:</b>		
	13.6.1	(a) the details referred to in Section 13.3, with the exception of (d) and (e);	Applicable	Clause 6.2
	13.6.2	(b) the performances referred to in Section 3 and any undesirable side-effects;	Applicable	Clause 5
	13.6.3	(c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;	Applicable	Clause 5
	13.6.4	(d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate	Applicable	Clause 6

		properly and safely at all times;		
13.6.5		(e) where appropriate, information to avoid certain risks in connection with implantation of the device;	Not applicable, since hearing aids are not implantable.	
13.6.6		(f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;	Applicable to aids that transmit signals such as RF CROS aids	Clause 4.5
13.6.7		(g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate details of appropriate methods of re-sterilization;	Not applicable, since hearing aids are not sterile devices.	
13.6.8		(h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses.	Applicable	None
		Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilizing must be such that, if correctly followed, the device will still comply with the requirements in Section I;		
13.6.9		(i) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);	Not applicable	
13.6.10		(j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation;	Not applicable, since hearing aids emit no radiation.	
		The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:		
13.6.11		(k) precautions to be taken in the event of changes in the performance of the device;	Applicable	None
13.6.12		(l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;	Applicable	None
13.6.13		(m) adequate information regarding the medicinal product or Products which the device in	Not applicable, since hearing aids administer	

		question is designed to administer, including any limitations in the choice of substances to be delivered;	no substances.	
	13.6.14	(n) precautions to be taken against any special, unusual risks related to the disposal of the device;	Not applicable, since disposal of hearing aids involves no special risk.	
	13.6.15	(o) medicinal substances incorporated into the device as an integral part in accordance with Section 7 4;	Not applicable, since hearing aids contain no medicinal substances.	
	13.6.18	(p) degree of accuracy claimed for devices with a measuring function.	Not applicable, since hearing aids are not measuring devices.	
14	14	Where conformity with the essential requirements must be based on clinical data, as in Section I(6), such data must be established in accordance with Annex X.	Not applicable, for hearing aids (but may be included).	

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