ASSISTIVE PRODUCT SPECIFICATION FOR PROCUREMENT

Hearing aids

Objective:

The objective of this specification is to help organizations in procuring good quality hearing aids that are durable and which assist individuals with hearing impairments to listen

World Health Organization

1. Product description

The purpose of this section is to provide specific key details relevant to the assistive product so that it is easily identifiable.	
Purpose of 1.1	Name of product as per WHO priority APL and/or commonly used names.
1.1 Name of product	Hearing aids
Purpose of 1.2	As per ISO 9999 classification and terminology document (refer https://www.iso.org/standard/60547.html).
1.2 ISO 9999 code	22 06 15 *Behind-the-ear hearing aids* Devices worn behind the ear to amplify sound Included are, e.g. headband hearing aids. For accessories and spare parts see ISO 9999 code 22 06 27 *Accessories for assistive products for hearing*
Purpose of 1.3	Describes the product type in clear, simple, easily understood language and the intended use in addressing functional needs.
1.3 Description and intended use	An electronic device that amplifies sound. Intended for people suffering from hearing loss. Its main function is to understand oral language and it also aids perception of environmental sounds. The device is portable and attached to the wearer's ear through an earmould, foam insert or other coupling method. Hearing aids vary in power and pattern of amplification, depending on the wearer's degree and type of hearing loss. Pre-programmed hearing aids are set to specific amplification patterns, appropriate to generic types of hearing loss, prior to fitting.
Purpose of 1.4	Refers to general characteristics of the assistive product that describes its appearance and components.
1.4 General features	Device body typically encloses microphone(s), receiver, amplification unit and power supply. Device body is coupled with an ear coupling system such as tubing and earmould. Batteries, that are either conventional or rechargeable, power the device and the battery is situated in the device body. Pre-programmed hearing aids have one or more listening programs, ear coupling system such as tubing (standard or slim) and earmould.
Purpose of 1.5	Refers to product models that are included in the specific APS.
1.5 Inclusion	• Behind-the-ear hearing aids. • Behind-the-ear digital hearing aids. • Behind-the-ear air-conduction hearing aids. • Pre-programmed behind-the-ear hearing aids. • Receiver in canal, slim tube, and standard tube fittings.
Purpose of 1.6	Refers to product models that are excluded in the specific APS.
1.6 Exclusion	• Analogue hearing aids. • In-the-ear, spectacle and body-worn hearing aids. • Bone conduction hearing aids.
Purpose of 1.7	Important, searchable words that relate to the specific assistive product.

1.7 Keywords	Communication, hearing, listening, hearing aids, self-programme, pre-programme, over-the-internet, over-the-counter.

2. Product requirements

The purpose of this section is to provide details of all applicable requirements relative to the specific assistive product. A requirement is mandatory and typically describes what a product should be able to do, how it should appear (product and packaging) etc. Only supply and service requirements considered applicable in procurement of hearing aids – pre-programmed and custom configuration.

2.1 Functional requirements

Purpose of 2.1		A functional requirement refers to technical details and other specific functionality that define what a product variation is supposed to accomplish. Per product variation, the requirement should describe the typical user, specific characteristics of the product (in addition to the general features above) as well as the requirements for standard configuration of the product. It is important to focus on performance requirements rather than form factors. It is important to have a clear and specific description of the typical users including e.g. health condition, functional limitation or demographics (range of age, body weight, height, etc). If applicable, specific context of use (e.g. indoor/outdoor, in noisy environment, etc) should be specified in the product variations.		
Item	**Product variations**	**Typical user**	**Specific characteristics**	**Requirements for standard configuration**
1	Behind-the-ear hearing aid with pre-configured ear inserts	Adults with mild to severe hearing loss (WHO 2004 criteria) in most communicative environments	Meet amplification needs for individuals with specific hearing loss configurations in the mild to severe range. Include pre-configured (stock or disposable) ear inserts that come in a variety of sizes.	Amplification frequency response and maximum output (OSPL) that meets requirements of standard prescription formulae (such as Desired Sensation Level v.5 or National Acoustics Laboratories NL2). Frequency range should be from 200 Hz to 4500 Hz (minimum). Overall, hearing aid should meet the parameters shown in Table 1.[1]
2	Behind-the-ear hearing aid with custom earmoulds	Adults with mild to profound hearing loss (WHO 2004 criteria) in most communicative environments	Meet amplification needs for individuals with specific hearing loss configurations in the mild to profound range. Include coupling system for custom made earmoulds.	Amplification frequency response and maximum output (OSPL) that meets requirements of standard prescription formulae (such as Desired Sensation Level v.5 or National Acoustics Laboratories NL2). Frequency range should be from 200 Hz to 4500 Hz

[1] *Preferred profile for hearing-aid technology suitable for low- and middle-income countries*, WHO 2017.

				(minimum). Overall, hearing aid should meet the parameters shown in Table 1.[1]
3	Pre-programmed behind-the-ear hearing aid with either custom earmoulds or pre-configured ear inserts	Adults with mild to severe hearing loss (WHO 2004 criteria) in most communicative environments	Meet generic amplification needs for individuals with specific targeted hearing loss configurations in the mild to severe range. Include pre-configured (stock or disposable) ear inserts that come in a variety of sizes or custom earmoulds.	Amplification frequency response and maximum output (OSPL) that meets requirements of standard prescription formulae (such as Desired Sensation Level v.5 or National Acoustics Laboratories NL2). Frequency range should be from 200 Hz to 4500 Hz (minimum). Overall, hearing aid should meet the parameters shown in Table 1[1].

Purpose of 2.2	Brief and clear description of general product performance requirements and overall qualities (e.g. stability, strength, durability, waterproof, etc).
2.2 General design requirements	Comfortable and easy to wear, fit a range of hearing loss configurations, permit measurement of sound output, are reliable and packaged in robust containers**Error! Bookmark not defined.**
Purpose of 2.3	Details of existing or in-progress national or international standards should be provided here, whether freely or commercially available.
2.3 Standards	*Current product standards for hearing aids:* IEC 60118 Electroacoustics - Hearing aids, several parts in this series may be applicable National standards for hearing aid products, if available, or refer to widely used standards, European Commission, International Electrotechnical Commission 60118 – series subsections for hearing aids https://www.iec.ch/dyn/www/f?p=103:22:4020285717437::::FSP_ORG_ID,FSP_LANG_ID:1301,25;, USA Food and Drug Administration CFR Title 21, Sec. 801.420 Device Labelling, and 801.421 Conditions for Sale. CE standards (or national equivalent) for medical devices should be met. *Also consider:* Guidelines for hearing aids and services for developing countries. 2nd ed. (WHO, 2004). Preferred profile for hearing-aid technology suitable for lower and middle-income countries (WHO, 2017).
Purpose of 2.4	A certificate of conformity confirms that a product conforms to applicable national and/or international regulations. If a certificate is required for the specific assistive product, this information should be requested, e.g., CE (Europe), COC (Japan), GCC (USA).

2.4 Certificate of conformity	A certificate that the product conforms with applicable national or international regulations and standards where the supplied country demands should be provided (for example, a declaration of conformity with the medical durable device directive or the medical durable device regulation of the European Union). If the product does not conform with applicable national or international regulations and standards, the supplier should provide a certificate that the product complies with the requirements in this call for tender and is safe and effective for use by the typical user. The certificate should specify the product, all applied standards, if any, and the name and contact information of the supplier and be provided with the tender. The certificate of conformity is a legal document and should be signed by an authorized person at the supplier. The certificate of conformity should be supplied in English and/or the official language(s) of the tendering jurisdiction.
Purpose of 2.5	Lists the relevant scope of information required to identify the appropriate size and weight of the assistive product in its standard configuration (specific dimensions may be given if appropriate).
2.5 Size and weight	Size and weight are not fixed but the hearing aid dimensions and mass should be indicated such that wearer comfort is assured.
Purpose of 2.6	Lists the relevant scope of information that should be provided to service providers (e.g. how to select, assemble, fit, adapt, follow up, maintain, repair, refurbish the assistive product). The desired language(s) in which the technical information should be provided should be stated.
2.6 Technical information (for service providers)	Information on how to select, assemble, fit, and adapt the hearing aid, and how to assemble and adapt the pre-programmed hearing aid should be provided. Instructions on how to maintain, service, repair and refurbish the hearing aid should be provided. The technical information should be provided in the official language(s) where the products are supplied and/or in English.
Purpose of 2.7	Lists the scope of information, and its format, that should be provided to end-users to show how to safely use the assistive product.
2.7 Instructions for use	A user manual with instructions for use of the hearing aid should be provided by the supplier. Instructions on how to safely and effectively use the product, and how to care, maintain and clean it should be included. The user manual is intended for the user and/or care-giver. The user manual should be supported by simple diagram/picture material, and the contents written at an appropriate reader comprehension level Maintenance and care advice should include information appropriate to the local community, such as dehumidification strategies (WHO, 2017). The user manual should be provided in print format (WHO, 2017) and preferably also be available online. The user manual should be provided in the official language(s) where the products are supplied and in English.
Purpose of 2.8	Refers to the various weather and other environmental conditions, e.g., temperatures, humidity, rain, snow, sunshine, that the assistive product should be able to withstand.

2.8 Environment of use	Hearing aids should be able to withstand various weather conditions, including light rain, snow, and dust. To ensure durability of hearing aids when exposed to water, humidity and/or dust, the Ingress Protection (IP) rating (a measure of device tolerance for such environments) should be considered if available and hearing aids with ratings appropriate for the end-user environment selected. A minimum Ingress Protection (IP) rating for dirt/dust and water resistance of 5/6 or greater is desirable. Should be able to function in ambient temperatures from +45 to -20 degrees Celsius and relative humidity ranging from 0% to 80% (WHO, 2004).
Purpose of 2.9	Refers to the duration of the warranty period and the details of the warranty the manufacturer/supplier should provide within the specified period.
2.9 Warranty	Provided normal reasonable use, the supplier should, during the warranty period and without extra expenses, repair parts which break during product delivery. This warranty comprises all spare parts and labour, except for normal wear and tear of the product. The warranty period should be a minimum of 1 year. The same should apply for any ear inserts, spare parts and/or accessories. The supplier should cover all transport when repairing the hearing aid. Following a reasonable written complaint, the supplier should repair or replace the product within 10 working days and not more than 30 working days or other specified.
Purpose of 2.10	Refers to the expected duration, in years, of the assistive product. Documents describing how this is ensured must be provided.
2.10 Lifespan	Given the purpose of use by typical device wearers, the hearing aid should be designed for a lifetime of at least 5 years. The supplier should provide information regarding the battery life for a typical user.
Purpose of 2.11	Lists the scope of information required in packaging and labeling the assistive product. Explains the state of assembly the assistive product should be in when received by the end-user.
2.11 Packaging, labelling, and state of assembly	Each hearing aid should be permanently marked with the name of the manufacturer or distributor, the model name, serial number and year of manufacture. Unless it is physically impossible to insert the battery incorrectly, a “+” symbol should be used to indicate the location of the positive terminal (WHO, 2017). The packaging should withstand handling during transport (2017). The hearing aid should be delivered fully assembled or assembled to such an extent that the remaining assembly can be carried out with the use of commonly available equipment. If any special tool is required, it should be included with the delivery.
Purpose of 2.12	Refers to additional product requirements, depending on the specific assistive product, e.g., material, corrosion-resistance, adjustability, foldability, etc.

2.12 Other product requirements	In the tender, the supplier should provide the following information about the hearing aid: • Cautionary statements regarding product safety (e.g., high levels of sound output; storage out of reach of small children and animals; proper disposal of batteries).

3. Supply and service requirements

From the information provided below, only those supply and service requirements considered applicable may be used in a procurement bid.

The purpose of this section is to describe key supply and service requirements that are needed in order to ensure that the assistive product is received in due time, operational, being maintained/repaired and refurbished.	
Purpose of 3.1	Lists the scope of information to be requested on how the assistive product will be transported to the place of delivery.
3.1 Transportation	Information on how the hearing aid(s) will be transported, and who should pay for the transportation, should be provided.
Purpose of 3.2	Specifies the time between placing an order and receiving delivery of the assistive product (e.g. that it should not exceed 30 calendar days).
3.2 Delivery time	The time between placing an order of up to 50 hearing aid(s) and receiving delivery of them should not exceed 30 working days.
Purpose of 3.3	Refers to the specific details of the various accessories and spare parts available for the assistive product, including pricing and availability.
3.3 Accessories and spare parts	The supplier should offer the following accessories: • Hearing aid storage container for the end-user. • Hearing aid cleaning tools (e.g., small brushes and wires). All parts that the hearing aid consists of, and which may be replaced at some stage, should be offered as spare parts. When an accessory consists of one part, the same part should not be offered both as an accessory and a spare part, but only as an accessory. When an accessory consists of several parts that can be replaced, all replaceable parts should be offered as spare parts. Spare parts should be made available for a period of at least 5 years after the last order of a hearing aid. The price of the spare parts should be offered per part and not per set or pair.
Purpose of 3.4	Provides information regarding required maintenance services the supplier will provide, including the timeframe and frequency.
3.4 Maintenance	Information about payment per hour, including definitions of when a job starts and finishes; travel expenses, from – to, fee per km, rules when several maintenance jobs are done on the same route; hotel bills; who should provide the spare parts; in cases where the job is done by a sub-supplier, the invoice should be sent by the supplier with the contract. The prices should be according to the contract. (More information may be requested to be provided.)
Purpose of 3.5	Provides information regarding required repairment services the supplier will provide, including the timeframe and frequency.

3.5 Repair	Information about payment per hour, including definitions of when a job starts and finishes; travel expenses, from – to, fee per km, rules when several maintenance jobs are done on the same route; hotel bills; who should provide the spare parts; in cases where the job is done by a sub-supplier, the invoice should be sent by the supplier with the contract. The prices should be according to the contract. (More information may be requested to be provided.)
Purpose of 3.6	Provides information regarding required refurbishment services the supplier will provide, including the timeframe and frequency.
3.6 Refurbishing	Information about payment per hour, including definitions of when a job starts and finishes; travel expenses, from – to, fee per km, rules when several maintenance jobs are done on the same route; hotel bills; who should provide the spare parts; in cases where the job is done by a sub-supplier, the invoice should be sent by the supplier with the contract. The prices should be according to the contract. (More information may be requested to be provided.)
Purpose of 3.7	Specifies if training service providers is required by suppliers, and the key elements included in the training (e.g. selection, assembly, fit, maintenance and repair of the assistive product). Refers to detailed training contents or materials, if available and applicable.
3.7 Training of service providers	Information about selecting, assembling, fitting, using and maintaining the hearing aid should be provided to the appropriately trained personnel.
Purpose of 3.8	Specifies if training users is required by suppliers, and the key elements included in the training (e.g. training to users should include fit, use, maintenance and cleaning of the assistive product). Refers to detailed training contents or materials, if available and applicable.
3.8 Training of users	Information on safe use, cleaning, maintenance and when to follow-up on hearing aids should be made available to users in paper form or electronically. Users should be encouraged to consult the appropriately trained personnel. Caregivers should be included in the training. Information regarding when a user should consult with the appropriately trained personnel regarding the use of hearings could be provided. Most training is provided through the manufacturer's instructions or online video.
Purpose of 3.9	Provides information regarding other supply and service requirements.
3.9 Other supply and service requirements	Not applicable in this call for tender.