EHIMA Guidance Document

- Classification of Hearing Aids and Accessories

- According to

REGULATION (EU) 2017/745 Medical Device Regulation (MDR)
US FDA requirements

Revision: 16
Issue date: Febr. 2026

EHIMA Guidance Document

Classification of Hearing aids and Accessories

Table of Contents

1. Introduction

The innovativeness of the Hearing Aid industry sometimes creates challenges in classifying Medical Devices and accessories according to Medical Device Regulation (EU) 2017/745 Medical Device Regulation (MDR) and US Code of Federal Regulations requirements.
This document serves as a guidance for the Hearing Aid Industry to create a harmonized way within Industry to classify devices in the same manner. The classification result might differ dependent upon the unique characteristics of the products A first issue was made within the prEN 50220 General requirements for hearing aids: EUROPEAN HEARING INSTRUMENT MANUFACTURERS ASSOCIATION Annex Z 1 published in June 1998.

2. Scope

This document serves as a guidance document when classifying Hearing Aids and Accessories according to Medical Device Regulation 2017/745 (MDR) and US CFR requirements. In addition “detachable parts” (See chapter 5) are mentioned for clarification.

3. Reference

3.1 EU

- REGULATION (EU) 2017/745 Medical Device Regulation (MDR)
- MDCG 2021-24 - Guidance on classification of medical devices

3.2 US

- SEC. 201. [21 U.S.C. 321] Definitions; generally
- FDA 21 CFR 820 Sec. 820.3 Definitions SUBCHAPTER H--MEDICAL DEVICES
- FDA 21 CFR 874. EAR, NOSE, AND THROAT DEVICES
- Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products Guidance for Industry and Food and Drug Administration Staff Mobile Medical Applications, Guidance for Industry and Food and Drug Administration Staff (Document issued on August 17, 2022)
- Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids, document number 2022-17230
- FDA 21 CFR 874.3400 Tinnitus masker (KLW code, Class 2 medical device, 510(k))
- FDA 21 CFR 874.3305 “Hearing Aid, Air Conduction with wireless technology” (Hearing Aid, Air-Conduction with Wireless Technology, class 2 medical device with special controls, 510(k) exempt)
- FDA 21 CFR 874.3300 “Hearing Aid, Air Conduction” (ESD code, class I MD, 510 exempt, non wireless hearing aids)
- FDA 21 CFR 874.3325 Self fitting air-conduction hearing aids (QUH code, Self-Fitting Air-Conduction Hearing Aid, Over the Counter 510(k))
- FDA 21 CFR 874.3340 Active implantable bone conduction hearing system (MAH code, Hearing aid, bone conduction, implanted, 510(k))
- FDA CFR 874.3300 hearing aid, bone conduction (LXB code, bone-conduction hearing aid, 510 (k))

4. Definition

4.1 Definitions according to REGULATION (EU) 2017/745 and MDCG 2021-3

‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

devices for the control or support of conception;
products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

‘accessory for a medical device’ means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s);

Software, which drives a device or influences the use of a device, shall fall within the same class as the device. If the software is independent of any other device, it shall be classified in its own right.

‘active device’ means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices.

Software shall also be deemed to be an active device;

‘custom-made device’ means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

However, mass-produced devices which need to be adapted to meet the specific requirements of any professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person shall not be considered to be custom-made devices;

Configurable device A configurable device is a device that consists of several components which can be assembled by the manufacturer in multiple configurations. Those individual components may be devices in themselves.

Configurable devices include computed tomography (CT) systems, ultrasound systems, anesthesia systems, physiological Monitoring systems, radiology information systems (RIS).

Patient matched (MDCG 2021-3)
A patient-matched device is defined as a medical device that meets the following requirements:
• it is matched to a patient's anatomy within a specified design envelope using techniques such as scaling of the device based on anatomic references, or by using the full anatomic features from patient imaging; and
• it is typically produced in a batch through a process that is capable of being validated and reproduced; and
• it is designed and produced under the responsibility of a manufacturer even though the design may be developed in consultation with an authorized healthcare professional.
Different from a custom-made device, these devices are typically produced in batches or through mass production and do not require a written prescription by an authorised person. In particular, a patient-matched medical device is held under the sole accountability of the manufacturer who is entirely responsible for the design, safety, performance and overall compliance of the device. Patient-matched medical devices must follow the 'standard' MDR regulatory pathway for placing on the market.

4.2 Definition according 21 CFR 800.30

Air-conduction hearing aid. An air-conduction hearing aid is a hearing aid that conducts sound to the ear through the air.

Hearing aid. A hearing aid is any wearable device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

Over-the-counter hearing aid. An over-the-counter (OTC) hearing aid is an air-conduction hearing aid that does not require implantation or other surgical intervention, and is intended for use by a person age 18 or older to compensate for perceived mild to moderate hearing impairment. The device, through tools, tests, or software, allows the user to control the hearing aid and customize it to the user's hearing needs. The device may use wireless technology or may include tests for self-assessment of hearing loss. The device is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online, provided that the device satisfies the requirements in this section.

Prescription hearing aid. A prescription hearing aid is a hearing aid that is not an OTC hearing aid as defined in this section or a hearing aid that does not satisfy the requirements in this section.

4.3 Definitions according 21 CFR 874.3340

Active implantable bone conduction hearing system. An active implantable bone conduction hearing system is a prescription device consisting of an implanted transducer, implanted electronics components, and an audio processor. The active implantable bone conduction hearing system is intended to compensate for conductive or mixed hearing losses by conveying amplified acoustic signals to the cochlea via mechanical vibrations on the skull bone.

4.4 Definitions according 21 CFR 874.3302

Bone-conduction hearing aid. A bone-conduction hearing aid is a wearable sound-amplifying device intended to compensate for impaired hearing and that conducts sound to the inner ear through the skull.

4.5 SEC. 201. [21 U.S.C. 321] Definitions; generally

The term "device" (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--
(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals,

4.6 21 CFR 820 Sec. 820.3 Definitions.

Finished device means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized

4.7 Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids, document number 2022-17230

Personal Sound Amplification Products (PSAPs) a PSAP is an electronic product intended for non-hearing-impaired people to amplify sounds in certain environments. A PSAP is not intended to aid with or compensate for impaired hearing.

4.8 FDA, Mobile Medical Applications, Guidance for Industry

For purposes of this guidance, a “mobile medical app” is a mobile app that meets the definition of device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) 4; and either is intended:
• to be used as an accessory to a regulated medical device; or
• to transform a mobile platform into a regulated medical device

For general wellness apps please consider the following guidance General Wellness: Policy for Low Risk Devices - Guidance for Industry and Food and Drug Administration Staff

5. General principles

Detachable part as component

- Detachable parts of HEARING AIDS, even if supplied separately (e.g. ear hooks, domes, wax guards etc.), are not considered as ACCESSORIES, but as component parts (ref IEC 60601-2-66 201.1.1)
- A HEARING AID includes all detachable parts that are essential for the performance of its INTENDED USE (ref IEC 60601-2-66 201.3.202)
- A detachable part supplied separately is a spare part when it is considered integral part of device essential for the performance of the device
  Spare part is neither device nor accessory on its own and thus bears no CE mark.

Detachable part as accessory

- A detachable part supplied separately can be classified by a manufacturer as an “ACCESSORY” if it meets the definition of an ACCESSORY as stated above.
- A detachable part classified as an ACCESSORY supplied separately to the device is classified on its own and thus bears CE mark.
- A detachable part not needed for the intended function of device is not an integral part of the device and therefore should be assessed whether it would need to be defined as accessory

6. Device classification and rules

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
1	**Hearing aids**							
1.1	Bone conduction hearing aid (no implant)	65091	Yes	Class IIa Rule 9 Not Accessory	Y214509	Class 2 874.3300 LXB	510(k) required	General: A bone conductor directly affects the output of hearing aids EU: Active medical device (active therapeutic device that administers energy and acts by converting electrical output to vibration). Classified as IIa. They are also sold separate from the hearing aid, and must therefore be CE marked.
1.3	Behind-the-ear (BTE) hearing aids (Non-Wireless)	BTE: 34671 RIC: 47169	Yes	Class IIa Rule 5 and 9 Not Accessory	BTE: Y2145060101 RIC: Y2145060102	Class 1 874.3300 ESD	510(k) Exempt	**US:** (special controls). The special controls for this device are (see 874.3300). EU: Active medical device (active therapeutic device that administers energy and acts by converting electrical output to vibration).
1.4	Behind-the-ear (BTE) hearing aids (Wireless)	BTE: 34671 RIC: 47169	Yes	Class IIa Rule 5 and 9 Not accessory	BTE: Y2145060101 RIC: Y2145060102	Class 2 874.3305 OSM	510(k) Exempt	**US:** (special controls). The special controls for this device are (see 874.3305). **EU:** Active medical device (active therapeutic device that administers energy and acts by converting electrical output to vibration).

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
1.6	CROS unit (contralateral unit)	59460	Yes	Class I without earpiece (Rule 1 and Rule 13) Accessory Class IIa if earpiece is used to hold the device in place (Rule 5 and 9) Accessory	Y2145599	Follow the device		**EU:** MDCG 2021-24 - Guidance on classification of medical devices
1.7	Dummy hearing aid	NA	No	Not Medical Device Not Accessory	NA	Not Medical Device	NA	**General:** Not functional, and therefore not a medical device Functional Demo devices placed on the market for demonstration purposes shall follow the classification of the relevant device.
1.8	Eyeglass hearing aid (EG)	47299	Yes	Class IIa Rule 9 Not Accessory	Y21450901	Class 1 874.3300 ESD	510(k) Exempt	**US:** (special controls). The special controls for this device are (see 874.3300). **EU:** EG is an active device.

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
1.11	In-the-ear (ITE) hearing aid (Non-wireless)	34672	Yes	Class IIa Rule 5 and 9 Not Accessory	Y2145060201	Class 1 874.3300 ESD	510(k) Exempt	**US:** (special controls). The special controls for this device are (see 874.3300).
1.12	In-the-ear (ITE) hearing aid (wireless)	34672 (ITE, HS) 41209 (ITC/CIC, IIC)	Yes	Class IIa Rule 5 and 9 Not Accessory	Y2145060201 (ITE) Y2145060202 (ITC) Y2145060203 (CIC)	Class 2 874.3305 OSM	510(k) Exempt	**US:** (special controls). The special controls for this device are (see 874.3305).
1.13	ITE kit / Faceplate	34672	Yes	Class IIa Rule 9 Not Accessory	Y215060201	Class 1 874.3300 LRB	510(k) Exempt	**EU:** Faceplates can be CE-marked, provided the assembler adheres to the faceplate manufacturer's instructions. **US:** Faceplates have their own product code = LRB
1.14	ITE kit / Faceplate (as component)	NA	No	Not Medical Device Not Accessory	NA	Not Medical Device	NA	**General:** Faceplate is a component of final hearing aid.
1.15	Tinnitus masker	38049 - Tinnitus masking	No	Class IIa Rule 9 Accessory	Y214599	Class 2 874.3400 KLW	510(k) required	**EU:** Tinnitus masker can be classified as a separate software device. It may also be considered as a software feature of hearing

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
		application software 43826 Air-conduction tinnitus masker, in-the-ear 40961 Bone-conduction tinnitus masker						aid. In this case, additional classification is not needed.
1.16	OTC self fitting, wireless hearing aid	BTE: 34671 RIC: 47169 34672 (ITE) 41209 (ITC/CIC)	YES	Class IIa Rule 5 and 9 Not Accessory	BTE: Y2145060101 RIC: Y2145060102 ITE Y2145060201 (ITC) Y2145060202 (CIC) Y2145060203	Class 2 874.3325 QUH/ prescription self fitting hearing aid QDD	510(k) required	

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	**Product**		**Product carry CE mark?**	**Classification / Rule/ Accessory?**		**Classification / Regulation/ Product Code**	**Pre-market approval**	
1.17	OTC pre set hearing aids	BTE: 34671 RIC: 47169 34672 (ITE) 41209 (ITC/CIC)	Yes	Class IIa Rule 5 and 9 Not Accessory	BTE: Y2145060101 RIC: Y2145060102 ITE Y2145060201 (ITC) Y2145060202 (CIC) Y2145060203	Class 2 874.3305 QUG	510(K) Exempt	
2	**Charger**							
2.1	Charger (for charging hearing aids including battery, as accessory)	17115	Yes	Class I (Rule1 and 13) Accessory	Y214580	Follows the device		**General:** The charger is classified as an accessory if the following conditions are met: The chargers are sold separately, are made specifically for charging batteries within the hearing aids and have specially designed connection pins for contact between the hearing aids and the charger. **EU:** MDCG 2021-24 - Guidance on classification of medical devices
2.2	Charger (for rechargeable batteries)	NA	No	Not Medical Device Not Accessory	NA	Not Medical Device	NA	**General:** The product is a multipurpose product and therefore is not considered a medical device or an accessory under the MDR or the US CFR. Nevertheless, it must

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
								still be CE-marked in accordance with the applicable EU legislations **EU:** MDCG 2021-24 - Guidance on classification of medical devices
2.3	Charger with cleaning function	17115	Yes	Class I (Rule1 and 13) Accessory	Y214580	Follows the device		**General:** The charger is classified as an accessory if the following conditions are met: the chargers are sold separately, are made specifically for charging batteries within the hearing aids and have specially designed connection pins for contact between the hearing aids and the charger. **EU:** MDCG 2021-24 - Guidance on classification of medical devices.
3	**Batteries**							
3.1	Battery (non rechargeable) multipurpose	NA	No	Not Medical Device Not Accessory	NA	Not Medical Device	NA	**General:** Multipurpose product and therefore not an accessory according to MDR and US CFR Follows applicable battery certification/regulation rules. **EU:** MDCG 2021-24 - Guidance on classification of medical devices
3.2	Battery	46539	Yes	Class I Rule 1	NA	Follows the device		**General:** If marketed as medical device specific battery the product becomes an

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
	(non rechargeable) Specific for medical device	Hearing aid battery		Accessory				accessory according to MDR and US CFR. Follows applicable battery certification/regulation rules, and also medical regulation rules
3.3	Battery (rechargeable) multipurpose	NA	No	Not Medical Device Not Accessory	NA	Not Medical Device	NA	**General:** Multipurpose product and therefore not an accessory according to MDR and US CFR. Follows applicable battery certification/regulation rules. **EU:** MDCG 2021-24 - Guidance on classification of medical devices
3.3	Battery integrated in the medical device (rechargeable) offered as spare part	NA	No	Not Medical Device Not Accessory Spare part	NA	Not Medical Device	NA	Follows applicable battery certification/regulation rules.
3.4	Battery (rechargeable) Specific for medical device	46539 Hearing aid battery	Yes	Class I Rule 1 Accessory	NA	Follows the device		**General:** If marketed as medical device specific battery the product becomes an accessory according to MDR and US CFR. Follows battery certification/regulation rules, and also medical regulation rules

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	**Product**		**Product carry CE mark?**	**Classification / Rule/ Accessory?**		**Classification / Regulation/ Product Code**	**Pre-market approval**	
3.5	Battery Tester	NA	No	Not Medical Device Not Accessory	NA	Not Medical Device	NA	**General:** Multipurpose product and therefore not an accessory according to MDR and US 21 CFR. **EU:** MDCG 2021-24 - Guidance on classification of medical devices
4	**Mobile app**							
4.1	Mobile APP (That does not drive or influence the device, doesn't claim medical purpose)	NA	NA	Not medical device, Not Accessory,	NA	Follow the device General Wellness information for mobile apps in US if not medical device		**General:** An APP that has no clinical and no diagnostic purpose and doesn't include a Remote-Control function of the **hearing aid**. Example: Apps used for remote consultation purposes only that do not influence the device
4.2	Mobile APP (that drives or influences the device)	60211/ 57885	Yes	Class IIa Rule 3.3 (SW follows the parent device), Rule 5 and 9 Not Accessory	Y214580/ Z12149092	Follow the device		**General:** This could be an APP including a Remote Control that changes a program setting or directly influences the SW parameters of the device
4.3	OTC mobile app (self fitting)	60211	YES	Class IIa	Y214580	Class 2	510(k) required	

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
				Rule 3.3 (SW follows the parent device), Rule 5 and 9 Not Accessory		874.3325 QUH		
4.4	App for remote fitting	60211	Yes	Class IIa Rule 3.3 (SW follows the parent device), Rule 5 and 9 Not Accessory	Y214580	Follow the device		**General:** This could be an APP including a Remote Control that changes a program setting or directly influences the SW parameters of the device Apps used for remote fitting consultation purposes only that do not influence the device see 4.1
5	**Software**							
5.1	Software (fitting)	60211	Yes	Class IIa Rule 3.3 (SW follows the parent device), Rule 5 and 9 Accessory	Y214580/ Z12149092	Follow the device		**General:** PC-based software for hearing aid fitting **EU:** MDCG 2021-24 - Guidance on classification of medical devices
5.2	Software (Embedded)	NA	No	Not Medical Device	NA	Not Medical Device		**General:** An integral part of the hearing aid, not medical device.

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
				Not Accessory				**EU:** MDCG 2021-24 - Guidance on classification of medical devices
5.3	Online hearing screener (not used for diagnosis purposes)	NA	No	Not Medical Device Not Accessory	NA	Not Medical Device		Provides only recommendation to contact an HCP as result, not used for diagnostic, fitting purpose, does not claim any clinical benefit or medical intended use
6	**Cleaning, maintenance**							
6.1	Cleaning fluid (not disinfecting, specifically to clean hearing aids/Earmolds by the user)	63385	Yes	Class I Rule 1 Not Accessory	V0799	Not Medical Device	NA	**EU:** Cleaning fluid is a medical device, but only if specifically developed to clean hearing aids etc. MDCG 2021-24 - Guidance on classification of medical devices
6.2	Cleaning fluids (that have disinfecting function to disinfect hearing aids/Earmolds by the user)	47631	Yes	Class IIb Rule 16 Not Accessory	V0799	Class I 880.6890 LRJ	510(K) Exempt	**General:** Specific cleaning fluids for disinfection **US:** exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in 880.9. EU: MDCG 2021-24 - Guidance on classification of medical devices

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
6.3	Maintenance tool (e.g brush tool, wax guard tool, dry capsule etc) Multipurpose	NA	No	Not Medical Device Not Accessory	NA	Not Medical Device	NA	**General:** Multipurpose product and therefore not a medical device or medical device accessory.
6.4	Maintenance tool (e.g brush tool, wax guard tool, dry capsule etc) Specific to use with medical device	Depends on the device e.g. 64217 - Hearing aid cleaning/drying container 64218 - Hearing aid floss 64219 - Hearing aid maintenance kit	Yes	Class I - Rule 1 for Cleaning; Class IIa - Rule 16 for disinfection Accessory	Depends on the device	Not Medical Device	NA	**General:** If specifically intended for cleaning or disinfecting of Hearing Aids the maintenance tool becomes a medical device according to Article 2(1). **EU:** MDCG 2021-24 - Guidance on classification of medical devices

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
		63684 - Ultraviolet hearing aid disinfecto						
6.5	Repair tool	NA	No	Not Medical Device Not Accessory	NA	Not Medical Device	NA	**General:** Repair tools are Multipurpose product and therefore not an accessory according to MDR . **EU:** MDCG 2021-24 - Guidance on classification of medical devices
6.6	Wax filter	NA	No	Not Medical Device Not Accessory	NA	Not Medical Device	NA	**General:** An integral part/component of the hearing aid.
7	**Ear piece**							
7.1	Acoustic tubing (for Earmolds, supplied with Earmold)	NA	No	Not Medical Device Not Accessory	NA	Not Medical Device	NA	**General:** If covered within a hearing aids technical file Acoustic tubing can be considered as integral parts due to IEC 60601-2-66:2019 §201.1.1. scope: "NOTE Detachable parts of hearing aids even if supplied separately (e.g. ear hooks, domes, wax guards etc.),

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
								are not considered as accessories but as component parts" The acoustic tubes are components, considered as integral parts of the hearing aid, and are at the same time also replaceable components for servicing. They maintain or restore the function of the device without changing its performance or safety characteristics or its intended purpose Due to the established design, development, and final testing of the entire hearing aid—including the listed components in all reasonable combinations—and the control of their quality through the established and maintained QMS, there is no possibility for these components or spare parts to significantly change the characteristics or performance of the medical device with respect to its already established conformity. Therefore, the items listed above are defined as **Components & Spare Parts**
7.2	Acoustic tubing (for Earmolds or	62260	Yes*	Class I	Y214580	Follow the device		**General:** If developed within a separate technical documentation, separate

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
	domes, supplied separately)			Rule 1 Accessory				conformity assessment of the dedicated technical file. **EU:** Tubing supplied separately can be classified and CE-marked separately after a separate conformity assessment if tubing can be used with “any” type of hearing aid. If shipped in bulk no CE-mark is needed.
7.3	Earmold (Plug – Medical Device)	41228	See Rationale : Yes if patient matched No if Custom-Made	Class I Rule 5 Accessory	Y214580	Unclassified (EWD) E – Hearing Protector		**EU:** Passive device for clinical conditions (e.g., perforated eardrum). Rule 5 remains Class I (no active connection). **Pathway Note:** CE/UDI required for *Patient-Matched*; Annex XIII for *CMD*. **FDA:** Class I (EWD - Hearing Protector) is "Unclassified" but treated as Class I under enforcement discretion .A passive device for clinical conditions (e.g, perforated eardrum) CE/UDI required for Patient-Matched; Annex XIII for CMD. FDA: Class I (EWD - Hearing Protector) is "Unclassified" but treated as Class I under enforcement discretion. MDR
7.4	Earmold (Accessory)	41228	See Rationale :	Class IIa Rule 5 Accessory	Y214580	LDG Class I Class I (LDG/OSM)		**EU:** Rule 5 elevation applies due to connection to Class IIa active device, even when supplied as an accessory.

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
			Yes if patient matched No if Custom-Made					**Pathway Note:** If manufacturer chooses *Patient-Matched*, CE & UDI are required. If *Custom-Made (CMD)*, CE/UDI are not used; Annex XIII statement & unique patient code are required. **FDA:** Code LDG/OSM Class I. Supplied separately to the hearing aids applicable for multiple variants of hearing aids across manufacturers. If *Custom-Made (CMD)*, CE/UDI are not used; Annex XIII statement & unique patient code are required.
7.5	Earmold (Integral part) supplied with HA	NA	No	NA	NA	Not Medical Device	NA	**General:** If covered within a hearing aids technical file Earmold, ear dome, ear tip, wax filter, earwire, hook, etc., can be considered as integral parts due to IEC 60601-2-66:2019 §201.1.1. scope: "NOTE Detachable parts of hearing aids even if supplied separately (e.g. ear hooks, domes, wax guards etc.), are not considered as accessories but as component parts"

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
								The earpieces are components, considered as integral parts of the hearing aid, and are at the same time also replaceable components for servicing. They maintain or restore the function of the device without changing its performance or safety characteristics or its intended purpose Due to the established design, development, and final testing of the entire hearing aid—including the listed components in all reasonable combinations—and the control of their quality through the established and maintained QMS, there is no possibility for these components or spare parts to significantly change the characteristics or performance of the medical device with respect to its already established conformity. Therefore, the items listed above are defined as **Components & Spare Parts**
7.6	Ear dome (As accessory)	62259	Yes	Class IIa Rule 5.1 Accessory	Y214580	Follow the device		**General:** If developed within a separate technical documentation, separate conformity assessment of the dedicated technical file

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
								EU: Invasive device intended for connection to a class IIa active device, are classified as class IIa.
7.8	Ear dome (As integral part)	NA	No	Not Medical Device Not Accessory	NA	Not Medical Device	NA	**General:** If covered within a hearing aids technical file Earmold, ear dome, ear tip, wax filter, earwire, hook, etc., can be considered as integral parts due to IEC 60601-2-66:2019 §201.1.1. scope: "NOTE Detachable parts of hearing aids even if supplied separately (e.g. ear hooks, domes, wax guards etc.), are not considered as accessories but as component parts" The earpieces are components, considered as integral parts of the hearing aid, and are at the same time also replaceable components for servicing. They maintain or restore the function of the device without changing its performance or safety characteristics or its intended purpose Due to the established design, development, and final testing of the entire hearing aid—including the listed

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
								components in all reasonable combinations—and the control of their quality through the established and maintained QMS, there is no possibility for these components or spare parts to significantly change the characteristics or performance of the medical device with respect to its already established conformity. Therefore, the items listed above are defined as **Components & Spare Parts**
7.9	Ear Hook (As integral part)	NA	No	Not Medical Device Not Accessory	NA	Not Medical Device	NA	**General:** If covered within a hearing aids technical file Earmold, ear dome, ear tip, wax filter, earwire, hook, etc., can be considered as integral parts due to IEC 60601-2-66:2019 §201.1.1. scope: "NOTE Detachable parts of hearing aids even if supplied separately (e.g. ear hooks, domes, wax guards etc.), are not considered as accessories but as component parts" The earpieces are components, considered as integral parts of the hearing aid, and are at the same time also replaceable

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
								components for servicing. They maintain or restore the function of the device without changing its performance or safety characteristics or its intended purpose Due to the established design, development, and final testing of the entire hearing aid—including the listed components in all reasonable combinations—and the control of their quality through the established and maintained QMS, there is no possibility for these components or spare parts to significantly change the characteristics or performance of the medical device with respect to its already established conformity. Therefore, the items listed above are defined as **Components & Spare Parts**
7.10	Impression material	44974	Yes	Class I Rule 5 Not Accessory	Y214580	Class 1 874.3300 LDG	510(k) Exempt	**General:** A substance that, although for temporary use, may have health and safety implications. **EU:** Impression material is invasive material in transient use. Hence classified as Class I.

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
								US: Product Code LDG relates to ear molds used for air conduction hearing aids.
7.11	Receiver in the Ear unit (As Accessory)	47169	Yes (placed on packaging)	Class IIa Rule 9 and/or 5 Accessory	Y2145060102	Follow the device		**General:** If developed within a separate technical documentation, separate conformity assessment of the dedicated technical file **EU:** An active device intended to administer energy in connection to a class IIa active device, are classified as class IIa
7.12	Receiver in the Ear unit (As integral part)	NA	No	Not Medical Device Not Accessory	NA	Not Medical Device	NA	**General:** Earmold, ear dome, ear tip, wax filter, earwire, hook, etc., can be considered as integral parts due to IEC 60601-2-66:2019 §201.1.1. scope: "NOTE Detachable parts of hearing aids even if supplied separately (e.g. ear hooks, domes, wax guards etc.), are not considered as accessories but as component parts" The earpieces are components, considered as integral parts of the hearing aid, and are at the same time also replaceable components for servicing. They maintain or restore the function of the device without

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
								changing its performance or safety characteristics or its intended purpose Due to the established design, development, and final testing of the entire hearing aid—including the listed components in all reasonable combinations—and the control of their quality through the established and maintained QMS, there is no possibility for these components or spare parts to significantly change the characteristics or performance of the medical device with respect to its already established conformity. Therefore, the items listed above are defined as **Components & Spare Parts**
7.13	protections used while making ear impressions (e.g. foams)	NA	No	Not Medical Device Not Accessory	NA	Not Medical Device	NA	**General:** Multipurpose device, used to make ear impressions for hearing aid industry and also for hearing protection, customized security ear pieces: non-medical
8	**Accessories/Detachable parts**							
8.1	Audio Shoe (supplied separately)	60259	Yes	Class I Rule 1 Accessory	Y214580	Follow the device		**General:** Audio shoe generically designed to work with many hearing aid models.

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
								Audio shoe is a detachable component that 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. It is specifically intended by the manufacturer of the accessory to be used together with a Medical Device. **EU:** MDCG 2021-24 - Guidance on classification of medical devices
8.2	Audio Shoe (If supplied with hearing Aid)	NA	No	Not Medical Device Not Accessory	NA	Follow the device		**General:** Audio shoe specifically designed for a defined hearing aid model. Audio shoe is a detachable component that can be removed from the hearing aid, and the hearing aid still works as intended by the manufacturer.
8.3	Wireless receiver	57961	Yes	Class I Rule 1 and 13 Accessory	Y214580	Follow the device		**General:** For FM receiver designed for physical connection to Hearing Aid) or detached. FM link adapter does <u>not</u> convert signal, is an active medical device. **EU:** MDCG 2021-24 - Guidance on classification of medical devices

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
8.7	PC (for programming)	NA	NA	Not Medical Device Not Accessory	NA	Not Medical Device	NA	**General:** Multipurpose product and therefore not an accessory. **EU:** MDCG 2021-24 - Guidance on classification of medical devices
8.8	Programming interface (e.g Hi Pro)	61462	Yes	Class I Rule 1 and 13 Accessory	Y214580	Follow the device		**General:** A programming device intended to be temporarily (transient) connected by wire/wireless to a Hearing aid transmitting predefined program into the hearing aid. . **EU:** MEDDEV 2.1/1 Apr 94 1.1f, 1.2
8.9	Programming Interface	57886	Yes	Class IIa Rule 3.3 -> Rule 5 and 9 Accessory	Y214580	Follow the device		**General:** A wireless programming device specifically intended to be used with Hearing Aid transmitting a program wirelessly by a signal (energy), that alters/manages the program to a hearing aid (active medical device class IIa) **EU:** MDCG 2021-24 - Guidance on classification of medical devices
8.10	Hardware Remote control (Required)	57885	Yes	Class IIa Follows the parent device	Y214580	Follow the device		**General:** A required remote control is an essential part of the hearing aid, since the remote control is required to fulfill the intended use of hearing aid and so follows the classification of parent device.

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
				Rule 5 and 9 Accessory				
8.11	Hardware Remote control (Optional/Accessory)	57885	Yes	Class I Rule 13 Accessory	Y214580	Follow the device		**General:** 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 Class I **EU:** It may be sold separately, and must be independently CE-marked.
8.12	Remote microphone (Dedicated for HA)	57886	Yes	Class I Rule 13 Accessory	Y214580	Follow the device		**General:** A dedicated microphone specifically designed and intended to be used with hearing aids. **EU:** MDCG 2021-24 - Guidance on classification of medical devices
8.13	Remote microphone (Multipurpose)	NA	No	Not Medical Device Not Accessory	NA	Not Medical Device	NA	**General:** Multipurpose product occasionally used in the medical environment and not specifically designed to be used with hearing aids **EU:** MDCG 2021-24 - Guidance on classification of medical devices Even though not a medical device it should still be CE-marked following RED (radio

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	**Product**		**Product carry CE mark?**	**Classification / Rule/ Accessory?**		**Classification / Regulation/ Product Code**	**Pre-market approval**	
								equipment directive, 2014/53/EU) and other applicable EU regulations
8.15	ALD (assistive listening device) (Group hearing aid or group auditory trainer)	57886	Yes	Class I Rule 1 and 13 Accessory	Y214580	Class 2 874.3320 LZI/EPF	510(K) Exempt	**General:** Examples are FM equipment, IR equipment, teleloop systems, auracast system, radio, TV. Depending on the intended use, ALDs is classified as medical device accessories when specifically intended to be used together with a medical device. **EU:** MDCG 2021-24 - Guidance on classification of medical devices
8.15	ALD (assistive listening device) Generic device, multipurpose	NA	No	NA	NA	NA	NA	**General:** Examples are FM equipment, IR equipment, teleloop systems, auracast system, radio, TV, multipurpose devices, compatible with medical and non medical products **EU:** MDCG 2021-24 - Guidance on classification of medical devices
9	**Spare parts**							
9.1	Spare part	NA	No	Not Medical Device Not Accessory	NA	Not Medical Device	NA	**General:** Spare parts (component or integral/detachable parts of hearing aid) for service/repair are not medical devices.

Classification		GMDN term	MDR classification acc. Annex VIII MDCG 2021-24 - Guidance on classification of medical devices		EMDN code	FDA classification		Comments and rationale for classification
No.	Product		Product carry CE mark?	Classification / Rule/ Accessory?		Classification / Regulation/ Product Code	Pre-market approval	
								EU: MDCG 2021-24 - Guidance on classification of medical devices
9.2	Tamperproof battery cover	NA	No	Not Medical Device Not Accessory	NA	Not Medical Device	NA	**General:** An integral part/component of the hearing aid.
9.3	Volume control cover	NA	No	Not Medical Device Not Accessory	NA	Not Medical Device	NA	**General:** An integral part/component of the hearing aid.