EHIMA Guidance Document

- Classification of Hearing Aids and Accessories

- According to
  - 93/42/EEC Medical Device Directive (MDD)
  - REGULATION (EU) 2017/745 Medical Device Regulation (MDR)
  - US FDA 21CFR800s requirements

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1. Introduction

The innovativeness of Hearing Aid industry is sometimes creating challenges in classifying Medical Devices and accessories according to Annex IX of the 93/42/EEC Medical Device Directive, REGULATION (EU) 2017/745 Medical Device Regulation (MDR) and US Code of Federal Regulations requirements.

This document serves as a guidance for Hearing Aid Industry to create a harmonized way within Industry to classify devices in the same manner.

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 Directive 93/42/EEC (MDD), Medical Device Regulation 2017/745 (MDR) and US CFR requirements.

Accessories falling under MDD definitions and US CFR definitions are covered.

For clarity some borderline examples of accessories not falling under the MDD are mentioned. They follow the definition of “Multipurpose products” acc to MEDDEV 2. 1/1 April 1994 1.1g

In addition “detachable parts” (See definition below) are mentioned as well for clarification.

3. References

3.1. EU

- 93/42/EEC Medical Device Directive Article 1 Definitions, scope
- REGULATION (EU) 2017/745 Medical Device Regulation (MDR)
- 93/42/EEC Medical Device Annex IX Classification criteria
- MEDDEV 2. 1/1 April 1994 Definition of "medical devices", Definition of "accessory"
- MEDDEV 2. 4/1 Rev. 9 June 2010, Classification of medical devices
- prEN 50220 General requirements for hearing aids: EUROPEAN HEARING INSTRUMENT MANUFACTURERS ASSOCIATION Annex Z 1 published in June 1998.
- EN 60601-2-66:2019 MEDICAL ELECTRICAL EQUIPMENT – Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems

3.2. US

- SEC. 201. [21 U.S.C. 321] Definitions; generally
- 21CFR820 Sec. 820.3 Definitions SUBCHAPTER H--MEDICAL DEVICES
- 21CFR874. EAR, NOSE, AND THROAT DEVICES
- Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products, Draft Guidance for Industry and Food and Drug Administration Staff (Document issued on: November 7, 2013)
- Mobile Medical Applications, Guidance for Industry and Food and Drug Administration Staff (Document issued on: February 2015)

4. Definitions

a. Definition according to chapter 201.1.1 Scope IEC 60601-2-66
ACCESSORY to HEARING AIDS in HOME HEALTHCARE ENVIRONMENT (e.g. remote control units, audio streamers, battery chargers, power supplies) can be tested according to the applicable standard, IEC 60065, IEC 60950-1, IEC 62368-1 or other applicable IEC safety standards. Alternatively, the general standard may be applied.
HEARING AIDS do not have a MAINS PART intended for connection to a.c. SUPPLY MAINS. The connection to SUPPLY MAINS of a HEARING AID system is covered by power supply, charger or other types of ACCESSORIES.
NOTE Detachable parts of HEARING AIDS even if supplied separately (e.g. ear hooks, domes, wax guards 205 ect.), are not considered as ACCESSORY, but as component parts.

b. 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, or..

c. 21CFR820 Sec. 820.3 Definitions.
(l)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….

d. Draft Guidance Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products
PSAPs are intended to amplify environmental sound for non-hearing-impaired consumers. They are intended to accentuate sounds in specific listening environments, rather than for everyday use in multiple listening situations. They are not intended to compensate for hearing impairment or to address listening situations that are typically associated with and indicative of hearing loss…

e. 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….

5. Classification		EU MDD 93/42/EEC Annex IX and MEDDEV 2.4/1 Rev 9 (Accessory - MEDDEV 2.1/1 Apr94)			FDA regulations		Comments and Rationale for Classification
No.	**Product**	**Classification/ Rule/ Accessory?**	**Product carry CE mark?**	**MDR Notes**	**Classification/ Regulation/ Product Code**	**Pre-market approval**	
1.1	Acoustical tubing (for Earmolds, supplied with Earmold)	Not Medical Device Not Accessory	No	No Change	Follow the device		**General:** Tubing is a detachable part (spare part) that may affect the acoustical properties of Earmolds, and hence the hearing aids. Tubing is part of a custom Earmold, and has gone through conformity assessment of the hearing aid.
1.2	Acoustical tubing (for Earmolds or domes, supplied separately)	Class I Rule 1 Accessory	Yes*	No Change	Follow the device		**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.
2.1	ALD (assistive listening device, excluding Group hearing aid or group auditory trainer)	Depends on intended use	Yes	No Change	Class 2 874.3320 LZI	510(K) Exempt	**General:** Examples are FM equipment, IR equipment, teleloop systems, radio, TV. Depending on the intended use, ALDs can be classified as medical device accessories. **EU:** MEDDEV 2.1/1 Apr 94 1.2
2.2	ALD (Group hearing aid or group auditory trainer)	Depends on intended use	Yes	No Change	Class 2 874.3320 EPF	510(K) Exempt	**EU:** MEDDEV 2.1/1 Apr 94 1.2
3.1	Audio Shoe (supplied separately)	Class I Rule 1 Accessory	Yes*	No Change	Follow the device		**General:** Audio shoe generically designed to work with many hearing aid models. 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:** MEDDEV 2.1/1 Apr 94 1.2

5. Classification		EU MDD 93/42/EEC Annex IX and MEDDEV 2.4/1 Rev 9 (Accessory - MEDDEV 2.1/1 Apr94)			FDA regulations		Comments and Rationale for Classification
No.	**Product**	**Classification/ Rule/ Accessory?**	**Product carry CE mark?**	**MDR Notes**	**Classification/ Regulation/ Product Code**	**Pre-market approval**	
3.2	Audio Shoe (If supplied with hearing Aid)	Not Medical Device Not Accessory	No	No Change	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.
4	Wireless receiver	Class I Rule 1 Accessory	Yes	No Change	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 and therefore is <u>not</u> an active medical device. **EU:** MEDDEV 2.1/1 Apr 94 1.2
5.1	Battery (primary cell)	Not Medical Device Not Accessory	No	No Change	Not Medical Device	NA	**General:** Multipurpose product and therefore not an accessory according to MDD and US CFR **EU:** MEDDEV 2.1/1 Apr 94 1.1g
5.2	Battery (primary cell)	Class I Rule 1 Accessory	Yes	No Change	Follows the device		**General:** If marketed as Hearing Aid battery the product becomes an accessory according to MDD and US CFR.
6.1	Battery (rechargeable)	Not Medical Device Not Accessory	No	No Change	Not Medical Device	NA	**General:** Multipurpose product and therefore not an accessory according to MDD and US CFR. **EU:** MEDDEV 2.1/1 Apr 94 1.1g
6.2	Battery (rechargeable)	Class I Rule 1 Accessory	Yes	No Change	Follows the device		**General:** If marketed as Hearing Aid battery the product becomes an accessory according to MDD and US CFR.
7	Battery Tester	Not Medical Device Not Accessory	No	No Change	Not Medical Device	NA	**General:** Multipurpose product and therefore not an accessory according to MDD and US 21 CFR. **EU:** MEDDEV 2.1/1 Apr 94 1.1g

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No.	**Product**	**Classification/ Rule/ Accessory?**	**Product carry CE mark?**	**MDR Notes**	**Classification/ Regulation/ Product Code**	**Pre-market approval**	
8	Bone conduction Hearing Aid (no implant)	Class IIa Rule 9 Not Accessory	Yes	No Change	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.
9.1	Behind-the-ear (BTE) hearing aids (Non-Wireless)	Class IIa Rule 9 Not Accessory	Yes	No Change	Class 1 874.3300 ESD	510(k) Exempt	**US:** Class I (general controls) for the air-conduction hearing aid. The air-conduction hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 874.9. **EU:** Active medical device (active therapeutic device that administers energy and acts by converting electrical output to vibration).
9.2	Behind-the-ear (BTE) hearing aids (Wireless)	Class IIa Rule 9 Not Accessory	Yes	No Change	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).
10	Body-worn hearing aids (BW)	Class IIa Rule 9 Not Accessory	Yes	No Change	Class 1 874.3300 ESD	510(k) Exempt	**US:** Class I (general controls) for the air-conduction hearing aid. The air-conduction hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 874.9. **EU:** Active medical device (active therapeutic device that administers energy and acts by converting electrical output to vibration).

5. Classification		EU MDD 93/42/EEC Annex IX and MEDDEV 2.4/1 Rev 9 (Accessory - MEDDEV 2.1/1 Apr94)			FDA regulations		Comments and Rationale for Classification
No.	**Product**	**Classification/ Rule/ Accessory?**	**Product carry CE mark?**	**MDR Notes**	**Classification/ Regulation/ Product Code**	**Pre-market approval**	
11.1	Charger (for rechargeable batteries)	Not Medical Device Not Accessory	No	No Change	Not Medical Device	NA	**General:** Multipurpose product and though not an accessory according to MDD and US CFR. **EU:** MEDDEV 2.1/1 Apr 94 1.1g
11.2	Charger (for charging hearing aids including battery, as integral part)	Not Medical Device Not Accessory	Yes	No Change	Not Medical Device	NA	**General:** Charger as integral part, not medical device by its own right. Cannot be sold separately.
11.3	Charger (for charging hearing aids including battery, as accessory)	Class I Rule 12 (MDR Rule 13) Accessory	Yes	No Change	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:** MEDDEV 2.1/1 Apr 94 1.2
12.1	Cleaning fluid (not disinfecting, to clean hearing aids/Earmolds by the user)	Class I Rule 1 Not Accessory	Yes	No Change	Not Medical Device	NA	**EU:** Cleaning fluid is a medical device, but only if specifically developed to clean hearing aids etc. Non-invasive. Rules 2,3,4 does not apply.
12.2	Cleaning fluids (that have disinfecting function to disinfect hearing aids/Earmolds by the user)	Class IIb Rule 15 Not Accessory	Yes	No Change	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:** MEDDEV 2.4/1 June 2012 Rev 9

5. Classification		EU MDD 93/42/EEC Annex IX and MEDDEV 2.4/1 Rev 9 (Accessory - MEDDEV 2.1/1 Apr94)			FDA regulations		Comments and Rationale for Classification
No.	**Product**	**Classification/ Rule/ Accessory?**	**Product carry CE mark?**	**MDR Notes**	**Classification/ Regulation/ Product Code**	**Pre-market approval**	
13	Cord (includes cord between receiver and Body worn)	Not Medical Device Not Accessory	No	No Change	Not Medical Device	NA	**General:** The cord is an integral part/component of the hearing aid. Spare part if sold separately.
14	CROS unit (including microphone and potentially a telecoil)	Class I Rule 12 (MDR Rule 13) Accessory	Yes*	No Change	Follow the device		**General:** An option, a detachable part and hence not an integral part of the hearing aid. **EU:** MEDDEV 2.1/1 Apr 94 1.2
15	Dummy hearing aid	Not Medical Device Not Accessory	No	No Change	Not Medical Device	NA	**General:** Not functional, and therefore not a medical device
16.1	Earmold (custom-made)	Class I Rule 5 Accessory	No	No Change	Follow the device		**General:** An Earmold (Earmould) is a detachable part that can affect safety. **EU:** Earmolds are invasive device connected to an active device. Custom-made Earmolds cannot be CE-marked, but must comply with the MDD, Annex VIII.
16.2	Earmold (As Accessory)	Class IIa Rule 5 Accessory	Yes*	No Change	Follow the device		**General:** An Earmold is a detachable part that can affect safety. **EU:** Earmolds are invasive device intended for connection to a class IIa active device, are classified as class IIa.
16.3	Earmold (As integral part)	Not Medical Device Not Accessory	No	No Change	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"

5. Classification		EU MDD 93/42/EEC Annex IX and MEDDEV 2.4/1 Rev 9 (Accessory - MEDDEV 2.1/1 Apr94)			FDA regulations		Comments and Rationale for Classification
No.	**Product**	**Classification/ Rule/ Accessory?**	**Product carry CE mark?**	**MDR Notes**	**Classification/ Regulation/ Product Code**	**Pre-market approval**	
17.1	Ear dome (As accessory)	Class IIa Rule 5 Accessory	Yes	No Change	Follow the device		**General:** An Earmold is a detachable part that can affect safety **EU:** Invasive device intended for connection to a class IIa active device, are classified as class IIa.
17.2	Ear dome (As integral part)	Not Medical Device Not Accessory	No	No Change	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"
18	Earphone (e,g used with body worn)	Class IIa Rule 9 Not Accessory	Yes	No Change	Follow the device		**General:** An earphone directly affects the output of body worn hearing aids. **EU:** Earphone is an active device. Is therefore classified as IIa. It is also sold separate from the hearing aid, and must therefore be CE-marked
19	Eyeglass hearing aid (EG)	Class IIa Rule 9 Not Accessory	Yes	No Change	Class 1 874.3300 ESD	510(k) Exempt	**US:** (1) Class I (general controls) for the air-conduction hearing aid. The air-conduction hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 874.9. **EU:** EG is an active device.
20.1	Eyeglass adaptor (As accessory)	Class IIa Rule 9 Accessory	Yes*	No Change	Follow the device		
20.2	Eyeglass adaptor (As integral part)	Not Medical Device Not Accessory	No	No Change	Not Medical Device	NA	An option, and hence an integral part of the hearing aid

5. Classification		EU MDD 93/42/EEC Annex IX and MEDDEV 2.4/1 Rev 9 (Accessory - MEDDEV 2.1/1 Apr94)			FDA regulations		Comments and Rationale for Classification
No.	**Product**	**Classification/ Rule/ Accessory?**	**Product carry CE mark?**	**MDR Notes**	**Classification/ Regulation/ Product Code**	**Pre-market approval**	
21.1	Ear Hook (As accessory)	Class I Rule 1 Accessory	Yes*	No Change	Follow the device		
21.2	Ear Hook (As integral part)	Not Medical Device Not Accessory	No	No Change	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"
22	Impression material	Class I Rule 5 Not Accessory	Yes	No Change	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. **US:** Product Code LDG relates to ear molds used for air conduction hearing aids.
23.1	In-the-ear (ITE) Hearing Aid (Custom-Made) (Non-wireless)	Class IIa Custom-Made Not Accessory	No	No Change	Class 1 874.3300 ESD	510(k) Exempt	**EU:** In general, hearing aids with custom shell are not Custom-Made medical device. If an operator assembles ITEs deviating from an approved manufacturer's instructions, such aids are classified as custom devices, cannot be CE-marked, but must comply with MDD, Annex VIII. This is an alternative way to classify custom products. Refers to Article 1 (d) definitions of custom-made devices first section stating "custom-made device" means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient." Intension in MDR 2017/745 is the same **EU:** MEDDEV 2.1/1 Apr 94 1.1c; (EU) 2017/745 Article 2, Sec 3.
23.2	In-the-ear (ITE) Hearing Aid (Custom-Made) (Wireless)	Class IIa Custom-Made Not Accessory	No	No Change	Class 2 874.3305 OSM	510(k) Exempt	

5. Classification		EU MDD 93/42/EEC Annex IX and MEDDEV 2.4/1 Rev 9 (Accessory - MEDDEV 2.1/1 Apr94)			FDA regulations		Comments and Rationale for Classification
No.	**Product**	**Classification/ Rule/ Accessory?**	**Product carry CE mark?**	**MDR Notes**	**Classification/ Regulation/ Product Code**	**Pre-market approval**	
23.3	In-the-ear (ITE) Hearing Aid (Non-wireless)	Class IIa Rule 5 or Rule 9 Not Accessory	Yes	No Change	Class 1 874.3300 ESD	510(k) Exempt	**EU:** ITE hearing aids are invasive devices.
23.4	In-the-ear (ITE) Hearing Aid (wireless)	Class IIa Rule 5 or Rule 9 Not Accessory	Yes	No Change	Class 2 874.3305 OSM	510(k) Exempt	**EU:** ITE hearing aids are invasive devices.
23.5	ITE kit / Faceplate	Class IIa Rule 5 Not Accessory	Yes	No Change	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
23.6	ITE kit / Faceplate (as component)	Not Medical Device Not Accessory	No	No Change	Not Medical Device	NA	**General:** Faceplate is a component of final hearing aid.
24.1	Maintenance tool (e.g brush tool, wax guard tool, etc)	Not Medical Device Not Accessory	No	No Change	Not Medical Device	NA	**General:** Multipurpose product and therefore not an accessory. **EU:** MEDDEV 2.1/1 Apr 94 1.1g
24.2	Maintenance tool (e.g brush tool, wax guard tool, etc)	Class I - Rule 1 for Cleaning; Class IIa - Rule 15 for disinfection Accessory	No	Rule 15 become Rule 16	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).
25.1	Mobile APP (That does not drive or influence the device)	Class I Rule 12 (MDR Rule 11) Accessory	Yes	Rule 11 for Software	Follow the device		**General:** An APP that has an intended purpose covered by MDD and has no diagnostic purpose and doesn't include a Remote-Control function of the **hearing aid**. **EU:** Annex IX sec. 1.4

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No.	**Product**	**Classification/ Rule/ Accessory?**	**Product carry CE mark?**	**MDR Notes**	**Classification/ Regulation/ Product Code**	**Pre-market approval**	
25.2	Mobile APP (that drives or influences the device)	Class IIa Rule 9 (MDR Rule 11) Accessory	Yes	Implement-ing rule 3.3 and/or classificat-ion rule 11	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 **EU:** Annex IX sec. 3.2
26	PC (for programming)	Not Medical Device Not Accessory	No	No Change	Not Medical Device	NA	**General:** Multipurpose product and therefore not an accessory. **EU:** MEDDEV 2.1/1 Apr 94 1.1g
27.1	Programming interface (e.g Hi Pro, NOAH link)	Class IIa Rule 5 Accessory	Yes	No Change	Follow the device		**General:** A programming device intended to be temporarily (transient) connected by wire to a Hearing aid transmitting predefined program into the hearing aid. For an In-The-Ear hearing aid the programming cable extends into the ear canal making it invasive. **EU:** Rule 5 applies. Rule 9 does not apply due to lack of therapeutic functionality. MEDDEV 2.1/1 Apr 94 1.1f, 1.2
27.2	Programming Interface (Wireless)	Class I Rule 12 (MDR Rule 13) Accessory	Yes	No Change	Follow the device		**General:** A wireless programming device specifically intended to be used with Hearing Aid transmitting a program wirelessly by a signal (energy), between a PC or similar device that alters/manages the program to a hearing aid (active medical device class IIa) without any significant change. **EU:** MEDDEV 2.1/1 Apr 94 1.2
28.1	Receiver in the Ear unit (As Accessory)	Class IIa Rule 5 Accessory	No	No Change	Follow the device		**EU:** As accessory, this could also be classified as IIa following the hearing aid device.

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No.	**Product**	**Classification/ Rule/ Accessory?**	**Product carry CE mark?**	**MDR Notes**	**Classification/ Regulation/ Product Code**	**Pre-market approval**	
28	Receiver in the Ear unit (As integral part)	Not Medical Device Not Accessory	No	No Change	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"
29.1	Remote control (Required)	Class IIa Rule 9 Not Accessory	Yes	No Change	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.
29	Remote control (Optional/Accessory)	Class I Rule 12 (MDR Rule 13) Accessory	Yes	No Change	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.
30.1	Remote microphone (Dedicated for HA)	Class I Rule 12 (MDR Rule 13) Accessory	Yes	No Change	Follow the device		**General:** A dedicated microphone specifically designed and intended to be used with hearing aids. **EU:** MEDDEV 2.1/1 Apr 94 1.2
30.2	Remote microphone (Multipurpose)	Not Medical Device Not Accessory	Yes	No Change	Not Medical Device	NA	**General:** Multipurpose product occasionally used in the medical environment and not specifically designed to be used with hearing aids **EU:** MEDDEV 2.1/1 Apr 94 1.1g Even though not a medical device it should still be CE-marked following RED (radio equipment directive, 2014/53/EU)

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No.	**Product**	**Classification/ Rule/ Accessory?**	**Product carry CE mark?**	**MDR Notes**	**Classification/ Regulation/ Product Code**	**Pre-market approval**	
31	Repair tool	Not Medical Device Not Accessory	No	No Change	Not Medical Device	NA	**General:** Repair tools are Multipurpose product and therefore not an accessory according to MDD. **EU:** MEDDEV 2.1/1 Apr 94 1.1g
32.1	Software (fitting)	Class IIa Rule 9 (MDR Rule 11) Accessory	Yes	Implement-ing rule 3.3 and/or classificat-ion rule 11	Follow the device		**General:** PC-based software for hearing aid fitting **EU:** MEDDEV 2.4/1 chapter 3.1.4
32.2	Software (Embedded)	Not Medical Device Not Accessory	No	No Change	Not Medical Device	NA	**General:** An integral part of the hearing aid, not medical device. **EU:** MEDDEV 2.4/1 chapter 3.1.4
33	Spare part	Not Medical Device Not Accessory	No	No Change	Not Medical Device	NA	**General:** Spare parts (component or integral/detachable parts of hearing aid) for service/repair are not medical devices. **EU:** MEDDEV 2.4/1 2.1/1 Apr 94 1.1b chapter 3.1.4
34	Tinnitus masker	Class IIa Rule 9 Accessory	No	No Change	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 aid. In this case, additional classification is not needed.
35	Tamperproof battery cover	Not Medical Device Not Accessory	No	No Change	Not Medical Device	NA	**General:** An integral part/component of the hearing aid.
36	Volume control cover	Not Medical Device Not Accessory	No	No Change	Not Medical Device	NA	**General:** An integral part/component of the hearing aid.
37	Wax filter	Not Medical Device Not Accessory	No	No Change	Not Medical Device	NA	**General:** An integral part/component of the hearing aid.

Notes: * If device is too small, CE mark can be placed on accompanying documents.