



EU - Declaration of Conformity

Manufacturer:	GN Hearing A/S Lautrupbjerg 7 DK-2750 Ballerup Denmark
Single Registration Number (SRN):	For legal manufacturer: DK-MF-000009536
Conformity Assessment Procedure (MDR):	Annex IX of Medical Device Regulation (MDR) 2017/745
Conformity Assessment Procedure (RED):	Annex II of Radio Equipment Directive (RED) 2014/53/EU
Identification of Notified Body (MDR):	DQS Medizinprodukte GmbH August-Schanz-Str. 21, D-60433 Frankfurt am Main, Germany Notified Body EC Code No. 0297
Identification of the EU-certificate (MDR):	Certificate ID 170781055
Identification of the Device:	Category: Refer to Appendix A Brand: Refer to Appendix A Model: Refer to Appendix A
Classification of the Device (MDR):	Class IIa. RIE/BTE: Rule 9. ITE/ITC: Rule 5 and 9
Declaration of Conformity validity date until new release or latest:	2023-12-31
Applied standards and normative standards:	
MDR:	EN/IEC 60118-0:2015, EN/IEC 60118-7:2005, IEC 60601-1-2:2014+A1:2020, EN/IEC 60118-13:2020, ISO 10993-1:2018, EN/ISO 14971:2019
RED:	Health & Safety: EN 62479:2010; EMC: EN 301 489-17:2020 V3.2.0, EN 301 489-1:2019 V2.2.3; Spectrum: EN 300 328:2019 V2.2.2, EN 300 422-4:2017 V2.1.1
RoHS:	EN 63000:2018, EN/IEC 62321-1:2013

GN Hearing A/S, the manufacturer hereby declare, under our sole responsibility, that the below-mentioned devices comply with the relevant provisions of:

- EU Council Regulation 2017/745 (MDR) Annex I - General Safety and Performance Requirements;
- EU Council Directive 2014/53/EU (RED) Article 3 - Essential Requirements;
- EU Council Directive 2011/65/EU (RoHS);

and their relevant transpositions into national laws of the EU Member States in which the below-mentioned devices are distributed.

Place and Date: Ballerup, Denmark, 2022-09-23

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Appendix A

The following listed categories and models are compliant to the requirements stated on page 1.

Category:

Air-Conduction Hearing Aid

Intended Purpose:

The hearing aid is intended to compensate for hearing impairment by amplifying and transmitting sound to the ear.

Brand	Family Name	Models	Product Form Factor (PFF)	Product Name	GMDN Code	Basic UDI-DI	CND
Amplifon	AMPLI-ENERGY	B 5 ON R M B 4 ON R M B 3 ON R M	CABR70 03	BTE	34671	57082960000012V	Y214506
Amplifon	AMPLI-ENERGY	B 5 ON R SP B 5 ON R P B 4 ON R SP B 4 ON R P B 3 ON R SP B 3 ON R P	CABR80 03	BTE	34671	57082960000012V	Y214506
Amplifon	AMPLI-ENERGY	5ONWLDEUPAG 5ONWLDMPAG 5ONWLDEHPAG 4ONWLDEUPAG 4ONWLDMPAG 4ONWLDEHPAG 3ONWLDEUPAG 3ONWLDMPAG 3ONWLDEHPAG	CAIR1 03	ITE	34672	570829600000253B	Y214599
Amplifon	AMPLI-ENERGY	5ONWLDUPAG 5ONWLDMPAG 5ONWLDLPAG 5ONWLDHPAG 4ONWLDUPAG 4ONWLDMPAG 4ONWLDLPAG 4ONWLDHPAG 3ONWLDUPAG 3ONWLDMPAG 3ONWLDLPAG 3ONWLDHPAG	CAIR1 03	ITC	41209	570829600000523E	Y214599
Audigy	AGXR-H 5	H561-DRW	CAR12A 03	RIE	47169	570829600000102 W	Y214599
Audigy	AGXR-H 5	H562-DRW	CAR13A 03	RIE	47169	570829600000102 W	Y214599
Audigy	AGXR-H 5	H561-DRWC	CAR46A 03	RIE	47169	570829600000102 W	Y214599
Audigy	AGXR-H 7	H761-DRW	CAR12A 03	RIE	47169	570829600000102 W	Y214599
Audigy	AGXR-H 7	H762-DRW	CAR13A 03	RIE	47169	570829600000102 W	Y214599
Audigy	AGXR-H 7	H761-DRWC	CAR46A 03	RIE	47169	570829600000102 W	Y214599
Audigy	AGXR-H 9	H961-DRW	CAR12A 03	RIE	47169	570829600000102 W	Y214599
Audigy	AGXR-H 9	H962-DRW	CAR13A 03	RIE	47169	570829600000102 W	Y214599
Audigy	AGXR-H 9	H961-DRWC	CAR46A 03	RIE	47169	570829600000102 W	Y214599
BeMore	XB	XB977-DWC XB971-DWC XB777-DWC XB771-DWC	CABR70 03	BTE	34671	57082960000012V	Y214506

Brand	Family Name	Models	Product Form Factor (PFF)	Product Name	GMDN Code	Basic UDI-DI	CND
		XB577-DWC XB571-DWC					
BeMore	XB	XB988-DWHC XB988-DWC XB788-DWHC XB788-DWC XB588-DWHC XB588-DWC	CABR80 03	BTE	34671	57082960000012V	Y214506
Danalogic	Actio	AT877-DWC	CABR70 03	BTE	34671	57082960000012V	Y214506
Danalogic	Actio	AT888-DWC AT888-DWHC	CABR80 03	BTE	34671	57082960000012V	Y214506
Jabra	Enhance Pro 10	EP161	CAR12A 04	RIE	47169	570829600000102 W	Y214599
Jabra	Enhance Pro 10	EP162	CAR13A 04	RIE	47169	570829600000102 W	Y214599
Jabra	Enhance Pro 10	EP161-C	CARR1 04	RIE	47169	570829600000102 W	Y214599

Category:

Air-Conduction Hearing Aid

Intended Purpose:

The self-fitting hearing aid is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. It is adjusted by the user to meet the user's hearing needs. No pre-programming of hearing test is necessary. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.

Brand	Family Name	Models	Product Form Factor (PFF)	Product Name	GMDN Code	BUDI-DI	CND
Jabra	Enhance	Jabra Enhance	C-5 WOE46 03 AEC01EG	OTC ITE	34672	570829600000583S	Y21599