



EU - Declaration of Conformity


Manufacturer:	GN Hearing A/S Lautrupbjerg 7 DK-2750 Ballerup Denmark
Single Registration Number (SRN):	DK-MF-000009536
Conformity Assessment Procedure (MDR):	Annex IX of Medical Device Regulation (MDR) 2017/745
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, Rule 3.3
Declaration of Conformity validity date until new release or latest:	2023-08-30
Applied standards and normative standards:	
MDR:	EN ISO 14971:2019, EN IEC 62304:2006 + A1:2015

We, the manufacturer hereby declare, under our sole responsibility, that the above-mentioned devices comply with the relevant provisions of:

- EU Council Regulation 2017/745 (MDR) Annex I - General Safety and Performance Requirements;

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

Place and Date: Ballerup, 2022-08-30

DocuSigned by:

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Christoph Schmid
Vice President
Product Management
GN Hearing A/S

DocuSigned by:

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Karen Bryde Frisk
Director Regulatory & Compliance
Corporate Quality
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Doc.: 0454440, Rev.B



Appendix A

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

Category:

Hearing aid device control application software

Intended Purpose:

The AGXR Attune app is intended to be a remote control and an assist tool for wireless AGXR hearing aids. When used as a remote control, the app can adjust the hearing aid in accordance with the settings selected by the hearing care professional. When used as an assist tool, the app provides the user with a connection to the hearing care professional, who can adjust the hearing aid settings remotely.

The Jabra Enhance Pro app is intended to be a remote control and an assist tool for wireless Jabra hearing aids. When used as a remote control, the app can adjust the hearing aid in accordance with the settings selected by the hearing care professional. When used as an assist tool, the app provides the user with a connection to the hearing care professional, who can adjust the hearing aid settings remotely.

The My Lively app is intended to be a remote control and an assist tool for wireless Lively hearing aids. When used as a remote control, the app can adjust the hearing aid in accordance with the settings selected by the hearing care professional. When used as an assist tool, the app provides the user with a connection to the hearing care professional, who can adjust the hearing aid settings remotely.

The BeMore app is intended to be a remote control and an assist tool for wireless BeMore hearing aids. When used as a remote control, the app can adjust the hearing aid in accordance with the settings selected by the hearing care professional. When used as an assist tool, the app provides the user with a connection to the hearing care professional, who can adjust the hearing aid settings remotely.

The Tuner app is intended to be a remote control and an assist tool for our wireless hearing aids. When used as a remote control, the app can adjust the hearing aid in accordance with the settings selected by the hearing care professional.

Brand	Models	Product Form Factor (PFF)	Product Name	GMDN Code	Basic UDI-DI	CND
AGXR	Attune	GAN 5	GAN	57855	570829600000433	N/A
Jabra	Enhance Pro	GAN 5	GAN	57885	570829600000433	N/A
Lively	My Lively	GAN 5	GAN	57885	570829600000433	N/A
Unbranded	BeMore	GAN 5	GAN	57885	570829600000433	N/A
Unbranded	Tuner	GAN 5	GAN	57885	570829600000433	N/A

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

Category:

Hearing aid device control application software

Intended Purpose:

The Jabra Enhance App is intended to perform self-fitting and remote control of the Jabra Enhance hearing aids, allowing the user to adjust the hearing aids to address their specific hearing needs.

Brand	Family Name	Models	Product Form Factor (PFF)	Product Name	GMDN Code	Basic UDI-DI	CND
Jabra	Enhance	Jabra Enhance APP	ROG1	OTC APP	57885	57082960000593U	N/A