EU Quality Management Certificate

This is to certify that the company

GN Hearing A/S

Lautrupbjerg 7
2750 Ballerup
Denmark

SRN: DK-MF-000009536

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	514627 MDR2017Q
Certificate ID	1000217750
Effective date	2025-02-13
Expiry date	2026-10-27
Frankfurt am Main,	2025-02-13

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of the certification can only be verified by the QR-code.

420.90 Version 7.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DK-MF-000009536
Certificate ID: 1000217750

Device categories and variants covered by this certificate:

Device category:	**Air conduction hearing aids (RIE), tinnitus maskers**
	MDA 0310 - Active non-implantable devices for ear, nose and throat
Product name:	RIE
Risk classification:	IIa
Basic-UDI-DI:	57082960000102W
Intended purpose:	The hearing aid is intended to compensate for hearing impairment by amplifying and transmitting sound to the ear. The Tinnitus Sound Generator Module is a tool to generate sounds to be used in a Tinnitus Management Program to temporarily relieve patients suffering from Tinnitus.

Device category:	**Hearing aid fitting/programming (FSW), application software**
	MDA 0315 - Software
Product name:	FSW
Risk classification:	IIa
Basic-UDI-DI:	57082960000032Z
Intended purpose:	Fitting Software is computer software that is intended to program a hearing aid according to the needs of the specific user.

Device category:	**Hearing aid remote control (GAN), application software**
	MDA 0315 - Software
Product name:	GAN
Risk classification:	IIa
Basic-UDI-DI:	570829600000433
Intended purpose:	The app is intended to be a remote control for wireless hearing aids made by GN independent of brand. The app is intended to be a remote control for wireless accessories made by GN independent of brand. The app is intended to be an assist tool for wireless hearing aids made by GN independent of brand. When used as a remote control, the app can adjust the hearing aid and/or accessories 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.

Device category:	**Air conduction hearing aids (BTE), tinnitus maskers**
	MDA 0310 - Active non-implantable devices for ear, nose and throat
Product name:	BTE
Risk classification:	IIa
Basic-UDI-DI:	57082960000012V
Intended purpose:	The hearing aid is intended to compensate for hearing impairment by amplifying and transmitting sound to the ear. The Tinnitus Sound Generator Module is a tool to generate sounds to be used in a Tinnitus Management Program to temporarily relieve patients suffering from Tinnitus.

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Device category:	**Hearing aid remote control application software (OTC APP)** MDA 0315 - Software
Product name:	OTC APP
Risk classification:	IIa
Basic-UDI-DI:	57082960000593U
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.

Device category:	**Air conduction hearing aids (OTC ITE)** MDA 0310 - Active non-implantable devices for ear, nose and throat
Product name:	OTC ITE
Risk classification:	IIa
Basic-UDI-DI:	57082960000583S
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.

Device category:	**Transducer module with receiver in the ear** MDA 0310 - Active non-implantable devices for ear, nose and throat
Product name:	TMRIE
Risk classification:	IIa
Basic-UDI-DI:	57082960000443F, 57082960000453H
Intended purpose:	The transducer is intended to convert the amplified electrical signal provided by the hearing aid into sound which is presented to the hearing aid wearer. The transducer is connected to a compatible hearing aid on one end and a coupler (dome/earmold/encased mold) on the other.

Device category:	**Earmoulds (custom-made)** MDA 0310 - Active non-implantable devices for ear, nose and throat
Product name:	EMD
Risk classification:	IIa
Basic-UDI-DI:	57082960000433D
Intended purpose:	The earmould is intended to be connected to a receiver tube, thin tube or tube of larger diameter on a hearing aid. The earmould is intended to ensure that the sound outlet of the hearing aid is placed in the ear canal.

Device category:	**Earmoulds (preformed)** MDA 0310 - Active non-implantable devices for ear, nose and throat
Product name:	EMD
Risk classification:	IIa
Basic-UDI-DI:	57082960000423B
Intended purpose:	The dome is intended to be connected to a receiver tube or thin tube on a hearing aid. The dome is intended to ensure that the sound outlet of the hearing aid is placed in the ear canal.

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Device category:	**Air conduction hearing aids (ITC), tinnitus maskers** MDA 0310 - Active non-implantable devices for ear, nose and throat
Product name:	ITC
Risk classification:	IIa
Basic-UDI-DI:	57082960000483P 57082960000613F
Intended purpose:	The hearing aid is intended to compensate for hearing impairment by amplifying and transmitting sound to the ear. The Tinnitus Sound Generator Module is a tool to generate sounds to be used in a Tinnitus Management Program to temporarily relieve patients suffering from Tinnitus.

Device category:	**Air conduction hearing aids (ITE), tinnitus maskers** MDA 0310 - Active non-implantable devices for ear, nose and throat
Product name:	ITE
Risk classification:	IIa
Basic-UDI-DI:	57082960000022X
Intended purpose:	The hearing aid is intended to compensate for hearing impairment by amplifying and transmitting sound to the ear. The Tinnitus Sound Generator Module is a tool to generate sounds to be used in a Tinnitus Management Program to temporarily relieve patients suffering from Tinnitus.

Examinations and tests performed:
514627_A208068_GNHearing420_11e_Report_MED20210531verified dated 2021-08-31
514627_A208068_TD ÄM MDR Hassium-FSW report 20210910verified dated 2021-09-22
514627_A208068_TDÄMMDRHassium-RIEreport20210819 dated 2021-08-21
514627_A210326MED_01 dated 2022-08-08
514627_A210326MED_01 dated 2022-08-10
514627_211337MED_TD GAN dated 2022-11-16
514627_ A212842MED_02 dated 2023-08-07
514627_A216666MED_ 03 Change Notification FSW2.1 dated 2025-02-10

Further conditions for or limitations to the validity of the certificate:
n/a

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Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2022-05-24	170780323	Addition of The Jabra Enhance App / OTC APP / The Jabra Enhance / OTC ITE
02	2022-08-16	170781004	Addition of: Earmoulds (custom-made), Earmoulds (preformed), Transducer module with receiver in the ear
03	2022-08-18	170781054	Addition the products “Air conduction hearing aids (ITC), tinnitus maskers” and “Air conduction hearing aids (ITE), tinnitus maskers”
04	2022-11-17	170781737	Modification of the description of intended purpose for hearing aid remote control (GAN)
05	2023-08-10	1000131115	Change of Certificate Template
06	2025-02-10	1000169819	Significant Change Notification TD review “FSW2.1”