EU Technical Documentation Assessment Certificate

This is to certify that the company

GN Hearing A/S

Lautrupbjerg 7
2750 Ballerup
Denmark

SRN: DK-MF-000009536

has established and maintains the required Technical Documentation in accordance with

Annex IX, Chapter II 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 Technical Documentation has been verified and confirmed in Conformity Assessment Procedures according to Article 52. The Technical Documentation is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

For placing devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter I and III is required.

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

Certificate registration no.	514627 MDR2017B
Certificate ID	1000129541
Effective date	2023-08-10
Expiry date	2026-10-27
Frankfurt am Main,	2023-08-10

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

DQS Medizinprodukte GmbH

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Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: SRN: DK-MF-000009536
Certificate ID: 1000129541

Device categories and variants covered by this certificate:

Device category:	**Air conduction hearing aids (RIE), tinnitus maskers**
Product name:	RIE
Models:	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**
Product name:	FSW
Models:	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**
Product name:	GAN
Models:	GAN
Risk classification:	IIa
Basic-UDI-DI:	57082960000433
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**
Product name:	BTE
Models:	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)**
Product name:	OTC APP
Models:	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)**
Product name:	OTC ITE
Models:	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**
Product name:	TMRIE
Models:	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)**
Product name:	EMD
Models:	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)**
Product name:	EMD
Models:	EMD
Risk classification:	IIa
Basic-UDI-DI:	57082960000423B

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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.

Device category:	**Air conduction Hearing aids (ITC), tinnitus maskers**
Product name:	ITC
Models:	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**
Product name:	ITE
Models:	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_TD ÄM MDR Hassium-FSW report 20210910verified dated 2021-09-22
514627_A208068_TDÄMMDRHassium-RIEreport20210819 dated 2021-08-21
514627_A208068_GNHearing420_11e_Report_MED20210531verified dated 2021-08-31
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

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	170780322	Addition of The Jabra Enhance App / OTC APP / The Jabra Enhance / OTC ITE
02	2022-08-16	170781003	Addition of: Earmoulds (custom-made), Earmoulds (preformed), Transducer module with receiver in the ear
03	2022-08-18	170781055	Addition of Reed
04	2022-11-17	170781738	Correction of model name from Reed to ITE and ITC, correction of UDI-DI
05	2022-11-17	170782105	Additon Basis-UDI-ID from Harper under ITC
06	2022-11-19	170782245	Modification of the description of intended purpose for hearing aid remote control (GAN)