



Doc.: 0477130, Rev. I

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 the Regulation (EU) 2017/745
Conformity Assessment Procedure (RED):	Annex II of the 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 ID 0297
Identification of the EU-certificate (MDR):	Certificate ID 1000217750
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. BTE/RIE: Rule 9, ITE/ITC: Rule 5 and 9

Common specifications:

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Applied standards and normative standards:

RED: Health & Safety: IEC 62311:2019
EMC: EN 301 489-17 V3.2.5, EN 301 489-3 V2.3.2, EN 301 489-1 V2.2.3;
Spectrum: EN 300 328 V2.2.2, EN 300 422-4 V2.1.1, EN 300 330 V2.1.1

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

- REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (MDR), as amended
- DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (RED), as amended
- DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (RoHS), as amended

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

Place and Date: Ballerup, Denmark 2025-07-18

Signed by:

Karen Bryde Frisk
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Karen Bryde Frisk

Director of Regulatory Affairs
Corporate Quality
GN Hearing A/S



Appendix A

The following 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	Product Name	Model	Product Form Factor (PFF)	Basic UDI-DI	GMDN Code	EMDN Code
ReSound	Enzo IA	BTE	EIX98-DWHC	LUBR90 04	57082960000012V	34671	Y2145060101
			EI998-DWHC				
			EI798-DWHC				
			EI598-DWHC				
			EI498-DWHC				
			EI398-DWHC				
ReSound	Nexia	BTE	NX977-DWC	CABR70 04	57082960000012V	34671	Y2145060101
			NX971-DWC				
			NX777-DWC				
			NX771-DWC				
			NX577-DWC				
			NX571-DWC				
ReSound	Nexia	BTE	NX477-DWC	CABR80 04	57082960000012V	34671	Y2145060101
			NX471-DWC				
			CX177-DWC				
			NX988-DWC				
			NX788-DWC				
			NX588-DWC				
			NX488-DWC				



Doc.: 0477130, Rev. I

Brand	Family Name	Product Name	Model	Product Form Factor (PFF)	Basic UDI-DI	GMDN Code	EMDN Code
ReSound	Nexia	ITC	NX9ITC-DWC-UP NX9ITC-DWC-MP NX9ITC-DWC-LP NX9ITC-DWC-HP NX7ITC-DWC-UP NX7ITC-DWC-MP NX7ITC-DWC-LP NX7ITC-DWC-HP NX5ITC-DWC-UP NX5ITC-DWC-MP NX5ITC-DWC-LP NX5ITC-DWC-HP NX4ITC-DWC-UP NX4ITC-DWC-MP NX4ITC-DWC-LP NX4ITC-DWC-HP	CAIR1 04	57082960000483P	41209	Y2145060202
ReSound	Nexia	ITC	NX9ITC-DW-UP NX9ITC-DW-MP NX9ITC-DW-LP NX9ITC-DW-HP NX7ITC-DW-UP NX7ITC-DW-MP NX7ITC-DW-LP NX7ITC-DW-HP NX5ITC-DW-UP NX5ITC-DW-MP NX5ITC-DW-LP NX5ITC-DW-HP NX4ITC-DW-UP NX4ITC-DW-MP NX4ITC-DW-LP NX4ITC-DW-HP	LHI12 04	57082960000483P	41209	Y2145060202



Doc.: 0477130, Rev. I

Brand	Family Name	Product Name	Model	Product Form Factor (PFF)	Basic UDI-DI	GMDN Code	EMDN Code
ReSound	Nexia	ITE	NX9ITE-DWC-UP NX9ITE-DWC-MP NX9ITE-DWC-HP NX7ITE-DWC-UP NX7ITE-DWC-MP NX7ITE-DWC-HP NX5ITE-DWC-UP NX5ITE-DWC-MP NX5ITE-DWC-HP NX4ITE-DWC-UP NX4ITE-DWC-MP NX4ITE-DWC-HP	CAIR1 04	57082960000022X	34672	Y2145060201
ReSound	Nexia	RIE	NX961-DRW NX761-DRW NX561-DRW NX461-DRW	CAR12A 04	57082960000102W	47169	Y2145060102
ReSound	Nexia	RIE	NX962-DRW NX762-DRW NX562-DRW NX462-DRW	CAR13A 04	57082960000102W	47169	Y2145060102
ReSound	Nexia	RIE	NX960S-DRWC NX760S-DRWC NX560S-DRWC NX460S-DRWC CX160S-DRWC	DURR1 04	57082960000102W	47169	Y2145060102



Doc.: 0477130, Rev. I

Brand	Family Name	Product Name	Model	Product Form Factor (PFF)	Basic UDI-DI	GMDN Code	EMDN Code
ReSound	Savi	RIE	SAX61-DRW	CAR12A 04	57082960000102W	47169	Y2145060102
			SA461-DRW				
			SA361-DRW				
			SA261-DRW				
ReSound	Savi	RIE	SAX62-DRW	CAR13A 04	57082960000102W	47169	Y2145060102
			SA462-DRW				
			SA362-DRW				
			SA262-DRW				
ReSound	Savi	RIE	SAX60-DRWC	DURR1B 04	57082960000102W	47169	Y2145060102
			SA460-DRWC				
			SA360-DRWC				
ReSound	Vivia	RIE	VIX61-DRW	CAR12A 04	57082960000102W	47169	Y2145060102
			VI961-DRW				
			VI761-DRW				
			VI561-DRW				
			VI461-DRW				
ReSound	Vivia	RIE	VIX62-DRW	CAR13A 04	57082960000102W	47169	Y2145060102
			VI962-DRW				
			VI762-DRW				
			VI562-DRW				
			VI462-DRW				
ReSound	Vivia	RIE	VIX60S-DRWC	DURR1A 04	57082960000102W	47169	Y2145060102
			VI960S-DRWC				



Doc.: 0477130, Rev. I

Brand	Family Name	Product Name	Model	Product Form Factor (PFF)	Basic UDI-DI	GMDN Code	EMDN Code
ReSound	Vivia	RIE	VI760S-DRWC	DURR1B 04	57082960000102W	47169	Y2145060102
			VI560S-DRWC				
			VI460S-DRWC				
			VI160S-DRWC				