

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, Chapter II 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 1000129541
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:	2026-02-01
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
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:

- REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, Annex I - General Safety and Performance Requirements (MDR)
- DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, Article 3 - Essential Requirements (RED)
- DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (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, 2024-02-01

DocuSigned by:

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Karen Bryde Frisk
Director Regulatory & Compliance
Corporate Quality
GN Hearing A/S

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	EMDN Code
ReSound	Nexia	NX977-DWC NX971-DWC NX777-DWC NX771-DWC NX577-DWC NX571-DWC NX477-DWC NX471-DWC	CABR70 04	BTE	34671	57082960000012V	Y2145060101
ReSound	Nexia	NX988-DWC NX788-DWC NX588-DWC NX488-DWC	CABR80 04	BTE	34671	57082960000012V	Y2145060101
ReSound	Nexia	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	ITC	41209	570829600000483P	Y2145060202
ReSound	Nexia	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	ITE	34672	570829600000022X	Y2145060201
ReSound	Nexia	NX961-DRW NX761-DRW NX561-DRW NX461-DRW	CAR12A 04	RIE	47169	570829600000102W	Y2145060102

Brand	Family Name	Models	Product Form Factor (PFF)	Product Name	GMDN Code	Basic UDI-DI	EMDN Code
ReSound	Nexia	NX962-DRW	CAR13A 04	RIE	47169	57082960000102W	Y2145060102
		NX762-DRW					
		NX562-DRW					
		NX462-DRW					
ReSound	Nexia	NX960S-DRWC	DURR1 04	RIE	47169	57082960000102W	Y2145060102
		NX760S-DRWC					
		NX560S-DRWC					
		NX460S-DRWC					
		CX160S-DRWC					