

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 QMS, Chapters I, III of the Regulation (EU) 2017/745
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. RIE/BTE: Rule 9. ITE/ITC: Rule 5 and 9

Common specifications:

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Applied standards and normative standards:

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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 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 2026-01-20

Signed by:


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Karen Bryde Frisk
Director of Regulatory Affairs
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	Model	Product Form Factor (PFF)	Product Name	GMDN Code	Basic UDI-DI	EMDN Code
ReSound	Key	KE4CIC-MP KE4CIC-LP KE4CIC-HP KE3CIC-MP KE3CIC-LP KE3CIC-HP	CAI10 03	ITC	41209	57082960000613F	Y2145060203
ReSound	LiNX Quattro	RE9CIC-MP RE9CIC-LP RE9CIC-HP RE7CIC-MP RE7CIC-LP RE7CIC-HP RE5CIC-MP RE5CIC-LP RE5CIC-HP	CAI10 03	ITC	41209	57082960000613F	Y2145060203
ReSound	Nexia	NX9CIC-MP NX9CIC-LP NX9CIC-HP NX7CIC-MP NX7CIC-LP NX7CIC-HP NX5CIC-MP NX5CIC-LP NX5CIC-HP NX4CIC-MP NX4CIC-LP NX4CIC-HP	CAI10 03	ITC	41209	57082960000613F	Y2145060203
ReSound	Savi	SA4CIC-MP SA4CIC-LP SA4CIC-HP SA3CIC-MP SA3CIC-LP SA3CIC-HP SA2CIC-MP SA2CIC-LP SA2CIC-HP	CAI10 03	ITC	41209	57082960000613F	Y2145060203
ReSound	Sensia	SN9CIC-MP SN9CIC-LP SN9CIC-HP SN7CIC-MP SN7CIC-LP SN7CIC-HP SN5CIC-MP SN5CIC-LP SN5CIC-HP SN4CIC-MP SN4CIC-LP SN4CIC-HP	CAI10 03	ITC	41209	57082960000613F	Y2145060203



Brand	Family Name	Model	Product Form Factor (PFF)	Product Name	GMDN Code	Basic UDI-DI	EMDN Code
ReSound	Vibrant	VB5CIC-MP VB5CIC-LP VB5CIC-HP	CA110 03	ITC	41209	57082960000613F	Y2145060203