Doc.: 0528410 Rev. A

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 Annex II & III of the Regulation (EU) 2017/745

(MDR):

Conformity Assessment Procedure Annex III of Radio Equipment Directive (RED)

(RED): 2014/53/EU

Identification of the Device: Category: Accessory

Brand: See Appendix Model: See Appendix

Classification of the Device (MDR): Class I, Rule 1 and 13

Declaration of Conformity validity date 2026-08-13

until new release or latest:

Applied standards and normative standards:

RED: Health & Safety: IEC 62368-1:2018, EN IEC 62479:2010;

EMC: ETSI EN 301 489-17 V3.2.6 (2023-06), ETSI EN 301 489-1 V2.2.3 (2019-11), IEC 62368-3:2017, EN

60601-1-2:2015+A1:2021;

Spectrum: ETSI EN 300 328 V2.2.2 (2019-07);

RoHS: EN IEC 63000:2018, IEC 63000:2016 + AMD1:2022, EN 62321-1:2013

GN Hearing A/S, the manufacturer hereby declare, under our sole responsibility, that the above-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 Member States in which the above-mentioned devices are distributed.

Place and Date: Ballerup, Denmark 2024-08-13

Karen Bryde Frisk

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DocuSigned by:

Karen Bryde Frisk

Director of Regulatory Affairs Corporate Quality GN Hearing A/S

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Appendix A

The following listed models are compliant to the requirements stated on page 1.

Category:

Accessory

Intended Purpose:

The GN Hearing A/S Multi-Mic+ is intended to be a wireless remote microphone or connection to an audio device for wireless GN Hearing A/S hearing aids.

When used as a remote microphone, the Multi-Mic+ is placed close to a person or a sound source and sends the voice or sound directly to the hearing aid.

When used as a connection to an audio device, the Multi-Mic+ is connected to the audio device through cable, Telecoil or an FM adapter and the sound is sent directly to the hearing aid.

The GN Hearing A/S Multi-Mic+ may also be used together with Approved Cochlear or Cochlear Bone Anchored Solutions AB Partner Products.

Approved Partner Product refers to specific products released and marketed by Cochlear or Cochlear Bone Anchored Solutions AB partners.

Any Approved Partner Product compatibility will be subject to and the sole responsibility of partner.

Brand	Family	Model	Item	Product	Product	GMDN	Basic UDI-DI	EMDN
	Name		Number	Form	Name	Code		Code
				Factor				
				(PFF)				
GN	N/A	MULTI-MIC+,SM-3P	23093300	SM-3P	MULTI-MIC+	57886	57082960000393N	Y214580
Hearing								
GN	N/A	MULTI-MIC+,SM-	23325800	SM-3P	MULTI-MIC+	57886	57082960000393N	Y214580
Hearing		3P,DEMO						