EU - Declaration of Conformity

Manufacturer:

Single Registration Number (SRN):

Conformity Assessment Procedure (MDR): Conformity Assessment Procedure (RED): GN Hearing A/S Lautrupbjerg 7 DK-2750 Ballerup Denmark

DK-MF-000009536

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

2026-03-05

Declaration of Conformity validity date

until new release or latest:

Applied standards and normative standards:

RED: Health & Safety: EN/IEC 62368-1:2020, EN/IEC 62311:2020; EMC: EN 301 489-17 V3.2.5, EN 301 489-1 V2.2.3; Spectrum: EN 300 328 V.2.2.2

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 2024-03-05

DocuSigned by: Cindie Vandfeldt

DADE3C9CA19E47C... Cindie Vandfeldt Regulatory Process Compliance Manager Corporate Quality GN Hearing A/S

Appendix A

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

Category:

Accessory

Intended Purpose:

The TV-Streamer+, is intended to be a wireless connection to a television or other audio device for our wireless hearing aids.

The TV-Streamer+ may also be used together with Approved Partner Products from Cochlear Ltd or Cochlear Bone Anchored Solutions AB.

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

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

Brand	Family Name	Model	ltem Number	Product Form Factor (PFF)	Product Name/Device Name	GMDN Code	Basic UDI-DI	EMDN Code
GN Hearing	N/A	TV-STREAMER+	22926500	SAS-4	TV-STREAMER+	57886	570829600004139	Y214580
GN Hearing	N/A	TV- STREAMER+,DEMO	22978400	SAS-4	TV-STREAMER+	57886	570829600004139	Y214580
GN Hearing	N/A	TV-STREAMER+,VA	22979700	SAS-4	TV-STREAMER+	57886	570829600004139	Y214580
Amplifon	N/A	TV- STREAMER+,AMPLI- TV	23047700	SAS-4	TV-STREAMER+	57886	570829600004139	Y214580