



## EU - Declaration of Conformity

<b>Manufacturer:</b>	GN Hearing A/S Lautrupbjerg 7 DK-2750 Ballerup Denmark														
<b>Single Registration Number (SRN):</b>	(to be defined)														
<b>Conformity Assessment Procedure (MDR):</b>	Annex II & III of Medical Device Regulation (MDR) 2017/745 Annex III of Radio Equipment Directive (RED) 2014/53/EU														
<b>Identification of Notified Body (RED):</b>	American Certification Body Inc. 6731 Whittier Ave, Suite C110, McLean VA 22101, USA Notified Body EC Code No. 1588														
<b>Identification of the EC-certificate (RED):</b>	Certificate No. ATCB021861, issue 2														
<b>Identification of the Device:</b>	<table> <tr> <td><b>Category:</b></td> <td>Accessory</td> </tr> <tr> <td><b>Type:</b></td> <td>Wireless Audio Streamer</td> </tr> <tr> <td><b>GMDN:</b></td> <td>57886</td> </tr> <tr> <td><b>BUDI-DI:</b></td> <td>See Appendix</td> </tr> <tr> <td><b>CND:</b></td> <td>See Appendix</td> </tr> <tr> <td><b>Brand:</b></td> <td>See Appendix</td> </tr> <tr> <td><b>Model:</b></td> <td>See Appendix</td> </tr> </table>	<b>Category:</b>	Accessory	<b>Type:</b>	Wireless Audio Streamer	<b>GMDN:</b>	57886	<b>BUDI-DI:</b>	See Appendix	<b>CND:</b>	See Appendix	<b>Brand:</b>	See Appendix	<b>Model:</b>	See Appendix
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**Classification of the Device (MDR):** Class I, Rule 1 and 13

**Declaration of Conformity validity date until new release or latest:** 2022-12-23

### Applied standards and normative standards:

**MDR:** IEC 60950-1:2005 + A2:2013, EN 60601-1-2:2007, ISO 14971:2007, EN/ISO 13485:2016, EN/ISO 15223-1:2016, EN 62304:2006, EN 1041+A1:2013, IEC 62479:2010, ISO 10993-5:2009, ISO 10993-10:2010

**RED:** Health & Safety: IEC 60950-1:2005 + A2:2013, EN 62479:2010;  
EMC: EN 301 489-17 V3.2.0, EN 301 489-1 V2.2.0;  
Spectrum: EN 300 328 V2.1.1

**RoHS:** EN 50581:2012, EN 62321-1:2013

We, the manufacturer hereby declare, under our sole responsibility, that the above-mentioned devices comply with the relevant provisions of:

- EU Council Regulation 2017/745 (MDR) Annex I - General Safety and Performance Requirements;
- EU Council Directive 2014/53/EU (RED) Article 3 - Essential Requirements;
- EU Council Directive 2011/65/EU (RoHS);

and their relevant transpositions into national laws of the Member States in which the above-mentioned devices are distributed.

Place and Date: Ballerup, 2021-05-26

DocuSigned by:

**Uffe Kjems Hansen**

Head of Category Management  
Product Management  
GN Hearing A/S

DocuSigned by:

**Amarjit Kaur Gill**

Vice President  
Corporate Quality  
GN Hearing A/S

0424220 Rev. B



## Appendix A

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

Brand	Name	Description	Part No.	Model (PFF)	GMDN Code	BUDI-DI	CND
Amplifon	AMPLI-TV	TV 2,AMPLIFON,EU	20926100	SAS-3	57886	57082960000 4139	TBD
Amplifon	AMPLI-TV	TV 2,AMPLIFON,AUS	21129800	SAS-3	57886	57082960000 4139	TBD
Amplifon	AMPLI-TV	TV 2,AMPLI-TV,EU	21373100	SAS-3	57886	57082960000 4139	TBD
Amplifon	AMPLI-TV	TV 2,AMPLI-TV,UK	21373200	SAS-3	57886	57082960000 4139	TBD
Amplifon	AMPLI-TV	TV 2,AMPLI-TV,AUS	21373300	SAS-3	57886	57082960000 4139	TBD
GN Hearing	TV STREAMER 2	TV 2,US	18181900	SAS-3	57886	57082960000 4139	TBD
GN Hearing	TV STREAMER 2	TV 2,AUS	18182000	SAS-3	57886	57082960000 4139	TBD
GN Hearing	TV STREAMER 2	TV 2,UK	18182100	SAS-3	57886	57082960000 4139	TBD
GN Hearing	TV STREAMER 2	TV 2,EU	18182200	SAS-3	57886	57082960000 4139	TBD
GN Hearing	TV STREAMER 2	TV STREAMER 2,COSTCO,US	OP603910	SAS-3	57886	57082960000 4139	TBD
GN Hearing	TV STREAMER 2	TV STREAMER 2,COSTCO,US,DEMO	OP603911	SAS-3	57886	57082960000 4139	TBD