



## 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. ATCB021862														
<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 Bluetooth Bridge</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 Bluetooth Bridge	<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
<b>Category:</b>	Accessory														
<b>Type:</b>	Wireless Bluetooth Bridge														
<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														

**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: EN 60950-1:2006 + A12:2011, EN/IEC 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: EN 60950-1:2006 + A12:2011, 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

0424780 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	PHONE CLIP PLUS	PHONE CLIP PLUS,AMPLIFON,EU	20926300	BTB-2	57886	570829600 004037	TBD
Amplifon	PHONE CLIP PLUS	PHONE CLIP PLUS,AMPLIFON,AUS	21129900	BTB-2	57886	570829600 004037	TBD
GN Hearing	PHONE CLIP PLUS	PHONE CLIP PLUS,US	18186300	BTB-2	57886	570829600 004037	TBD
GN Hearing	PHONE CLIP PLUS	PHONE CLIP PLUS,AUS	18186400	BTB-2	57886	570829600 004037	TBD
GN Hearing	PHONE CLIP PLUS	PHONE CLIP PLUS,UK	18186500	BTB-2	57886	570829600 004037	TBD
GN Hearing	PHONE CLIP PLUS	PHONE CLIP PLUS,EU	18186600	BTB-2	57886	570829600 004037	TBD