



EU - Declaration of Conformity

Manufacturer:	GN Hearing A/S Lautrupbjerg 7 DK-2750 Ballerup Denmark														
Single Registration Number (SRN):	(to be defined)														
Conformity Assessment Procedure (MDR):	Annex II & III of Medical Device Regulation (MDR) 2017/745 Annex III of Radio Equipment Directive (RED) 2014/53/EU														
Identification of Notified Body (RED):	American Certification Body Inc. 6731 Whittier Ave, Suite C110, McLean VA 22101, USA Notified Body EC Code No. 1588														
Identification of the EC-certificate (RED):	Certificate No. ATCB021865, issue 2														
Identification of the Device:	<table> <tr> <td>Category:</td> <td>Accessory</td> </tr> <tr> <td>Type:</td> <td>Assistive Listening Device</td> </tr> <tr> <td>GMDN:</td> <td>57886</td> </tr> <tr> <td>BUDI-DI:</td> <td>See Appendix</td> </tr> <tr> <td>CND:</td> <td>See Appendix</td> </tr> <tr> <td>Brand:</td> <td>See Appendix</td> </tr> <tr> <td>Model:</td> <td>See Appendix</td> </tr> </table>	Category:	Accessory	Type:	Assistive Listening Device	GMDN:	57886	BUDI-DI:	See Appendix	CND:	See Appendix	Brand:	See Appendix	Model:	See Appendix
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Type:	Assistive Listening Device														
GMDN:	57886														
BUDI-DI:	See Appendix														
CND:	See Appendix														
Brand:	See Appendix														
Model:	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: IEC 60950-1:2005 + A2:2013, EN 60601-1-2:2007/AC:2010, ISO 14971:2007, EN/ISO 13485:2016, EN/ISO 15223-1:2016, IEC 62304:2006, IEC 62133:2012, EN 1041+A1:2013, IEC 62479:2010, ISO 10993-5:2009, ISO 10993-10:2010

RED: Health & Safety: EN 60950-1:2006 + A2:2013, EN 62479:2010;
EMC: EN 301 489-17 V2.2.1, EN 301 489-1 V1.9.2;
Spectrum: EN 300 328 V1.9.1, EN 300 422-4 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

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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	MULTI MIC	MULTI MIC,AMPLIFON,EU	20926500	SM-2P	57886	57082960000 393N	TBD
Amplifon	MULTI MIC	MULTI MIC,AMPLIFON,AUS	21130000	SM-2P	57886	57082960000 393N	TBD
GN Hearing	MULTI MIC	MULTI MIC,GEN,US	19081000	SM-2P	57886	57082960000 393N	TBD
GN Hearing	MULTI MIC	MULTI MIC,GEN,AUS	19081100	SM-2P	57886	57082960000 393N	TBD
GN Hearing	MULTI MIC	MULTI MIC,GEN,UK	19081200	SM-2P	57886	57082960000 393N	TBD
GN Hearing	MULTI MIC	MULTI MIC,GEN,EU	19081300	SM-2P	57886	57082960000 393N	TBD