



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 II of Radio Equipment Directive (RED) 2014/53/EU														
Identification of the Device:	<table> <tr> <td>Category:</td> <td>Accessory</td> </tr> <tr> <td>Type:</td> <td>Hearing Aid Charger</td> </tr> <tr> <td>GMDN:</td> <td>17115</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:	Hearing Aid Charger	GMDN:	17115	BUDI-DI:	See Appendix	CND:	See Appendix	Brand:	See Appendix	Model:	See Appendix
Category:	Accessory														
Type:	Hearing Aid Charger														
GMDN:	17115														
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, 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

0424310 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
AGXR	PREMIUM CHARGER	PKG,CHGR PREM2,C-1,AGX,CFF1,US	21588800	C-1	17115	57082960000163A	TBD
AGXR	PREMIUM CHARGER	PKO,CHGR PREM3,C-1,AGX,CFF1,US	21592400	C-1	17115	57082960000163A	TBD
AGXR	PREMIUM CHARGER	PKG,CHG KIT,AGX,PREM3,CFF3,US	21593700	C-1	17115	57082960000163A	TBD
AGXR	PREMIUM CHARGER	PKG,CHG KIT,AGX,PREM,MFI,XL,US	21604700	C-1	17115	57082960000163A	TBD
AGXR	PREMIUM CHARGER	PKG,CHGR PREM3,C-1,AGX,CFF1,US	21790200	C-1	17115	57082960000163A	TBD
Amplifon	PREMIUM CHARGER	PKG,CHG KIT,AMPLIFON,AUS	21604800	C-1	17115	57082960000163A	TBD
Amplifon	PREMIUM CHARGER	PKG,CHG KIT,AMPLIFON,EU	21604900	C-1	17115	57082960000163A	TBD
Amplifon	PREMIUM CHARGER	PKG,CHG KIT,AMPLIFON,UK	21741700	C-1	17115	57082960000163A	TBD
Amplifon	PREMIUM CHARGER	PKG,CHGR PREM2,C-1,AMP,CFF2,EU	21761100	C-1	17115	57082960000163A	TBD
Amplifon	PREMIUM CHARGER	PKG,CHGR PREM2,C-1,AMP,CFF2,UK	21761300	C-1	17115	57082960000163A	TBD
Amplifon	PREMIUM CHARGER	PKO,CHGR PMV3,C-1,AMPL,CFF2,EU	21843000	C-1	17115	57082960000163A	TBD
Amplifon	PREMIUM CHARGER	PKO,CHGR PMV3,C-1,AMPL,CFF2,UK	21843300	C-1	17115	57082960000163A	TBD
Amplifon	PREMIUM CHARGER	PKO,CHGR PMV3,C-1,AMPL,CFF3,EU	21858800	C-1	17115	57082960000163A	TBD
Amplifon	PREMIUM CHARGER	PKO,CHGR PMV3,C-1,AMPL,CFF3,UK	21859000	C-1	17115	57082960000163A	TBD
GN Hearing	PREMIUM CHARGER	CHARGER,LXR,GENERIC,RS INSERT	20863700	C-1	17115	57082960000163A	TBD
GN Hearing	PREMIUM CHARGER	DUM,FUNC,CHARGER,AP5,LUXOR	20928300	C-1	17115	57082960000163A	TBD
GN Hearing	PREMIUM CHARGER	CHARGER,LXR,GENERIC,BT INSERT	21126200	C-1	17115	57082960000163A	TBD
GN Hearing	PREMIUM CHARGER	CHGR PREM2,C-1,GEN,CFF1	21539600	C-1	17115	57082960000163A	TBD
GN Hearing	PREMIUM CHARGER	CHGR PREM2,C-1,GEN,CFF2	21539900	C-1	17115	57082960000163A	TBD
GN Hearing	PREMIUM CHARGER	CHGR PREM3,C-1,GEN,CFF1	21569700	C-1	17115	57082960000163A	TBD
GN Hearing	PREMIUM CHARGER	CHGR PREM3,C-1,GEN,CFF2	21570000	C-1	17115	57082960000163A	TBD
GN Hearing	PREMIUM CHARGER	CHGR PREM3,C-1,GEN,CFF3	21587600	C-1	17115	57082960000163A	TBD
GN Hearing	PREMIUM CHARGER	CHGR PREM3,C-1,GEN,CFF4	21587800	C-1	17115	57082960000163A	TBD
GN Hearing	PREMIUM CHARGER	CHGR PREM3,C-1,GEN,CFF1,CN	21648800	C-1	17115	57082960000163A	TBD
GN Hearing	PREMIUM CHARGER	CHGR PREM3,C-1,GEN,CFF2,CN	21649000	C-1	17115	57082960000163A	TBD



Brand	Name	Description	Part No.	Model (PFF)	GMDN Code	BUDI-DI	CND
GN Hearing	PREMIUM CHARGER	CHGR PREM3,C-1,GEN,CFF3,CN	21649300	C-1	17115	57082960000163A	TBD
GN Hearing	PREMIUM CHARGER	CHGR PREM3,C-1,GEN,CFF4,CN	21649400	C-1	17115	57082960000163A	TBD
GN Hearing	PREMIUM CHARGER	CHGR PREM3,C-1,GEN,CFF2,LOANE	21765400	C-1	17115	57082960000163A	TBD
GN Hearing	PREMIUM CHARGER	CHGR PREM3,C-1,GEN,CFF2,DEMO	21765600	C-1	17115	57082960000163A	TBD
GN Hearing	PREMIUM CHARGER	PKO,CHGR PREM3,C-1,GEN,CFF2,EU	21871600	C-1	17115	57082960000163A	TBD
GN Hearing	PREMIUM CHARGER	PKO,CHGR PREM3,C-1,GEN,CFF2,US	21871700	C-1	17115	57082960000163A	TBD
GN Hearing	PREMIUM CHARGER	PKO,CHGR PREM3,C-1,GEN,CFF2,UK	21871800	C-1	17115	57082960000163A	TBD
Jabra	PREMIUM CHARGER	PKO,CHGR PM3,C-1,JBRPM,CFF2,EU	22033000	C-1	17115	57082960000163A	TBD
Jabra	PREMIUM CHARGER	PKO,CHGR PM3,C-1,JBRPM,CFF2,UK	22033200	C-1	17115	57082960000163A	TBD
Jabra	PREMIUM CHARGER	PKO,CHGR PM3,C-1,JBRPM,CFF2,US	22033400	C-1	17115	57082960000163A	TBD
Specsavers	PREMIUM CHARGER	PKG,CHG KIT,SPECSAVERS,XL,UK	21606600	C-1	17115	57082960000163A	TBD
Specsavers	PREMIUM CHARGER	PKG,CHG KIT,SPECSAVERS,XL,AUS	21606700	C-1	17115	57082960000163A	TBD