



## 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 II of Radio Equipment Directive (RED) 2014/53/EU														
<b>Identification of the Device:</b>	<table> <tr> <td><b>Category:</b></td> <td>Accessory</td> </tr> <tr> <td><b>Type:</b></td> <td>Hearing Aid Charger</td> </tr> <tr> <td><b>GMDN:</b></td> <td>17115</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>	Hearing Aid Charger	<b>GMDN:</b>	17115	<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>	Hearing Aid Charger														
<b>GMDN:</b>	17115														
<b>BUDI-DI:</b>	See Appendix														
<b>CND:</b>	See Appendix														
<b>Brand:</b>	See Appendix														
<b>Model:</b>	See Appendix														
<b>Classification of the Device (MDR):</b>	Class I, Rule 1 and 13														
<b>Declaration of Conformity validity date until new release or latest:</b>	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

0424290 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
ReSound	PREMIUM CHARGER	CHARGER,LXR,RESOUND	20472100	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	CHARGER,LXR,VA	20896300	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	CHGR PREM2,C-1,RS,CFF1	21539400	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	CHGR PREM2,C-1,RS,VA,CFF1	21539700	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	CHGR PREM2,C-1,RS,CFF2	21539800	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	CHGR PREM3,C-1,RS,CFF1	21569500	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	CHGR PREM3,C-1,RS,VA,CFF1	21569800	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	CHGR PREM3,C-1,RS,CFF2	21569900	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	CHGR PREM3,C-1,RS,CFF3	21587400	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	CHGR PREM3,C-1,RS,VA,CFF3	21587700	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKG,CHGR PREM2,C-1,RS,CFF1,US	21588900	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKG,CHGR PREM2,C-1,RS,CFF1,UK	21589000	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKG,CHGR PREM2,C-1,RS,CFF1,EU	21589100	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKO,CHGR PREM3,C-1,RS,CFF1,US	21592500	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKG,CHGR PREM3,C-1,RS,CFF1,UK	21592600	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKG,CHGR PREM3,C-1,RS,CFF1,EU	21592700	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKG,CHG KIT,RS,PREM3,CFF3,US	21593800	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKG,CHGR PREM3,C-1,RS,CFF3,UK	21593900	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKG,CHGR PREM3,C-1,RS,CFF3,EU	21594000	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKG,CHG KIT,RS,PREM,MFI,XL,US	21605100	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKG,CHG KIT,CO,PREM,MFI,XL,US	21605200	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKG,CHG KIT,RS,PREM,MFI,XL,UK	21605300	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKG,CHG KIT,RS,PREM,MFI,XL,EU	21605400	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKG,CHG KIT,RS,PREM,MFI,XL,AUS	21605500	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKG,CHG KIT,CO,PREM,MFI,XL,AUS	21605600	C-1	17115	57082960000163A	TBD

Brand	Name	Description	Part No.	Model (PFF)	GMDN Code	BUDI-DI	CND
ReSound	PREMIUM CHARGER	PKG,CHG KIT,RS,PREM,MFI,XL,GDS	21605700	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKG,CHG KIT,RS,PREM,MFI,XL,KR	21605800	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKG,CHG KIT,RS,PREM,MFI,XL,BR	21605900	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	CHGR PREM3,C-1,RS,CFF1,CN	21648600	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	CHGR PREM3,C-1,RS,CFF2,CN	21648900	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	CHGR PREM3,C-1,RS,CFF3,CN	21649100	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKG,CHGR PREM3,C-1,RS,CFF1,US	21790300	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKO,CHGR PREM3,C-1,RS,CFF3,US	21810900	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKO,CHGR PREM3,C-1,RS,CFF3,UK	21811000	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKO,CHGR PREM3,C-1,RS,CFF3,EU	21811100	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKG,CHGR PREM3,C-1,CO,CFF2,EU	21849500	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKG,CHGR PREM3,C-1,CO,CFF2,US	21849700	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKG,CHGR PREM3,C-1,CO,CFF2,UK	21849900	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	PKG,CHG KIT,CO,PREM3,CFF3,US	21973300	C-1	17115	57082960000163A	TBD
ReSound	PREMIUM CHARGER	CHGR PRMV2,C-1,RS,VA,CFF1,DEMO	21996700	C-1	17115	57082960000163A	TBD
ReSound/F UJI	PREMIUM CHARGER	CHARGER,LXR,RESOUND,FUJI	21302700	C-1	17115	57082960000163A	TBD
ReSound/F UJI	PREMIUM CHARGER	CHGR PREM3,C-1,RS,FUJI,CFF3	21587900	C-1	17115	57082960000163A	TBD