



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

0424320 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 | STANDARD CHARGER | CHGR STD,C-2,RS,CFF1 | 21340800 | C-2 | 17115 | 57082960000163A | TBD |
| ReSound | STANDARD CHARGER | CHGR STD,C-2,RS,CFF2 | 21465300 | C-2 | 17115 | 57082960000163A | TBD |
| ReSound | STANDARD CHARGER | PKG,CHGR STD,C-2,RS,CFF1,US | 21625000 | C-2 | 17115 | 57082960000163A | TBD |
| ReSound | STANDARD CHARGER | PKG,CHGR STD,C-2,RS,CFF1,UK | 21625100 | C-2 | 17115 | 57082960000163A | TBD |
| ReSound | STANDARD CHARGER | PKG,CHGR STD,C-2,RS,CFF1,EU | 21625200 | C-2 | 17115 | 57082960000163A | TBD |
| ReSound | STANDARD CHARGER | PKG,CHGR STD,C-2,RS,CFF2,US | 21668600 | C-2 | 17115 | 57082960000163A | TBD |
| ReSound | STANDARD CHARGER | PKG,CHGR STD,C-2,KS10,CFF2,US | 21668700 | C-2 | 17115 | 57082960000163A | TBD |
| ReSound | STANDARD CHARGER | PKG,CHGR STD,C-2,RS,CFF2,EU | 21668800 | C-2 | 17115 | 57082960000163A | TBD |
| ReSound | STANDARD CHARGER | PKG,CHGR STD,C-2,RS,CFF2,UK | 21668900 | C-2 | 17115 | 57082960000163A | TBD |
| ReSound | STANDARD CHARGER | PKG,CHGR STD,C-2,KS10,CFF2,EU | 21669000 | C-2 | 17115 | 57082960000163A | TBD |
| ReSound | STANDARD CHARGER | PKG,CHGR STD,C-2,KS10,CFF2,UK | 21669100 | C-2 | 17115 | 57082960000163A | TBD |
| ReSound | STANDARD CHARGER | PKG,CHGR STD,C-2,CO,CFF2,EU | 21848900 | C-2 | 17115 | 57082960000163A | TBD |
| ReSound | STANDARD CHARGER | PKG,CHGR STD,C-2,CO,CFF2,US | 21849100 | C-2 | 17115 | 57082960000163A | TBD |
| ReSound | STANDARD CHARGER | PKG,CHGR STD,C-2,CO,CFF2,UK | 21849300 | C-2 | 17115 | 57082960000163A | TBD |