



## EU - Declaration of Conformity

|   |  |                  |           |              |                     |              |       |                 |              |             |              |               |              |               |              |
|---|--|------------------|-----------|--------------|---------------------|--------------|-------|-----------------|--------------|-------------|--------------|---------------|--------------|---------------|--------------|
| <b>Manufacturer:</b>  | GN Hearing A/S<br>Lautrupbjerg 7<br>DK-2750 Ballerup<br>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<br>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;<br>EMC: EN 301 489-17 V3.2.0, EN 301 489-1 V2.2.0;<br>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 Kjens Hansen**

Head of Category Management  
Product Management  
GN Hearing A/S

DocuSigned by:

**Amarjit Kaur Gill**

Vice President  
Corporate Quality  
GN Hearing A/S

0424300 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 |
|---------|-----------------|--------------------------------|----------|-------------|-----------|-----------------|-----|
| Beltone | PREMIUM CHARGER | CHARGER,LXR,BT,AMAZE           | 20623200 | C-1         | 17115     | 57082960000163A | TBD |
| Beltone | PREMIUM CHARGER | CHGR PREMV2,C-1,BT,CFF1        | 21539500 | C-1         | 17115     | 57082960000163A | TBD |
| Beltone | PREMIUM CHARGER | CHGR PREMV3,C-1,BT,CFF1        | 21569600 | C-1         | 17115     | 57082960000163A | TBD |
| Beltone | PREMIUM CHARGER | CHGR PREMV3,C-1,BT,CFF4        | 21587500 | C-1         | 17115     | 57082960000163A | TBD |
| Beltone | PREMIUM CHARGER | PKG,CHGR PREM2,C-1,BT,CFF1,US  | 21589600 | C-1         | 17115     | 57082960000163A | TBD |
| Beltone | PREMIUM CHARGER | PKG,CHGR PREM2,C-1,BT,CFF1,EU  | 21589700 | C-1         | 17115     | 57082960000163A | TBD |
| Beltone | PREMIUM CHARGER | PKO,CHGR PREM3,C-1,BT,CFF1,US  | 21593200 | C-1         | 17115     | 57082960000163A | TBD |
| Beltone | PREMIUM CHARGER | PKG,CHGR PREM3,C-1,BT,CFF1,EU  | 21593300 | C-1         | 17115     | 57082960000163A | TBD |
| Beltone | PREMIUM CHARGER | PKG,CHG KIT,BT,PREM3,CFF4,US   | 21594500 | C-1         | 17115     | 57082960000163A | TBD |
| Beltone | PREMIUM CHARGER | PKG,CHGR PREM3,C-1,BT,CFF4,EU  | 21594600 | C-1         | 17115     | 57082960000163A | TBD |
| Beltone | PREMIUM CHARGER | PKG,CHG KIT,BT,PREM,MFI,XL,US  | 21606000 | C-1         | 17115     | 57082960000163A | TBD |
| Beltone | PREMIUM CHARGER | PKG,CHG KIT,BT,PREM,MFI,XL,EU  | 21606100 | C-1         | 17115     | 57082960000163A | TBD |
| Beltone | PREMIUM CHARGER | PKG,CHG KIT,BT,PREM,MFI,XL,AUS | 21606200 | C-1         | 17115     | 57082960000163A | TBD |
| Beltone | PREMIUM CHARGER | PKG,CHG KIT,BT,PREM,MFI,XL,GDS | 21606300 | C-1         | 17115     | 57082960000163A | TBD |
| Beltone | PREMIUM CHARGER | PKG,CHG KIT,BT,PREM,MFI,XL,KR  | 21606400 | C-1         | 17115     | 57082960000163A | TBD |
| Beltone | PREMIUM CHARGER | PKG,CHG KIT,BT,HBM,PREM,MFI,XL | 21606800 | C-1         | 17115     | 57082960000163A | TBD |
| Beltone | PREMIUM CHARGER | CHGR PREMV3,C-1,BT,CFF1,CN     | 21648700 | C-1         | 17115     | 57082960000163A | TBD |
| Beltone | PREMIUM CHARGER | CHGR PREMV3,C-1,BT,CFF4,CN     | 21649200 | C-1         | 17115     | 57082960000163A | TBD |
| Beltone | PREMIUM CHARGER | PKG,CHGR PREM3,C-1,BT,CFF1,US  | 21790400 | C-1         | 17115     | 57082960000163A | TBD |
| Beltone | PREMIUM CHARGER | PKO,CHGR PREM3,C-1,BT,CFF4,US  | 21811200 | C-1         | 17115     | 57082960000163A | TBD |
| Beltone | PREMIUM CHARGER | PKO,CHGR PREM3,C-1,BT,CFF4,EU  | 21811300 | C-1         | 17115     | 57082960000163A | TBD |
| Beltone | PREMIUM CHARGER | PKG,CHG KIT,HBM,PREM3,CFF4,US  | 21963500 | C-1         | 17115     | 57082960000163A | TBD |