



EU - Declaration of Conformity

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|---|--|------------------|-----------|--------------|---------------------|--------------|-------|-----------------|--------------|-------------|--------------|---------------|--------------|---------------|--------------|
| 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:

D8C4F5850B9C4D8

Uffe Kjems Hansen

Head of Category Management
Product Management
GN Hearing A/S

DocuSigned by:

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Amarjit Kaur Gill

Vice President
Corporate Quality
GN Hearing A/S

0424360 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 | DESKTOP CHARGER | CHGR DSKTP,C-3,BT,CFF1 | 21655801 | C-3 | 17115 | 57082960000163A | TBD |
| Beltone | DESKTOP CHARGER | CHGR DSKTP,C-3,BT,CFF4 | 21655804 | C-3 | 17115 | 57082960000163A | TBD |
| Beltone | DESKTOP CHARGER | PKO,C-3,BT,CFF4,US | 21791900 | C-3 | 17115 | 57082960000163A | TBD |
| Beltone | DESKTOP CHARGER | PKO,C-3,BT,CFF4,EU | 21792000 | C-3 | 17115 | 57082960000163A | TBD |
| Beltone | DESKTOP CHARGER | PKG,C-3,BT,CFF4,US | 21900700 | C-3 | 17115 | 57082960000163A | TBD |
| Beltone | DESKTOP CHARGER | PKO,C-3,BT,CFF1,US | 21971700 | C-3 | 17115 | 57082960000163A | TBD |
| Beltone | DESKTOP CHARGER | PKO,C-3,BT,CFF1,EU | 21971900 | C-3 | 17115 | 57082960000163A | TBD |
| Beltone | DESKTOP CHARGER | PKG,C-3,BT,CFF1,US | 21972700 | C-3 | 17115 | 57082960000163A | TBD |