



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>Wireless Remote Control</td> </tr> <tr> <td>GMDN:</td> <td>57885</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:	Wireless Remote Control	GMDN:	57885	BUDI-DI:	See Appendix	CND:	See Appendix	Brand:	See Appendix	Model:	See Appendix
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Type:	Wireless Remote Control														
GMDN:	57885														
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/IEC 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

0424740 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	REMOTE CONTROL 2	RC-2,DIRECT,BT,US	18205000	RC-2	57885	5708296000 0373J	TBD
Beltone	REMOTE CONTROL 2	RC-2,DIRECT,BT,AUS	18240900	RC-2	57885	5708296000 0373J	TBD
Beltone	REMOTE CONTROL 2	RC-2,DIRECT,BT,UK	18241000	RC-2	57885	5708296000 0373J	TBD
Beltone	REMOTE CONTROL 2	RC-2,DIRECT,BT,EU	18241100	RC-2	57885	5708296000 0373J	TBD