



## 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>Wireless Remote Control</td> </tr> <tr> <td><b>GMDN:</b></td> <td>57885</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>	Wireless Remote Control	<b>GMDN:</b>	57885	<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>	Wireless Remote Control														
<b>GMDN:</b>	57885														
<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

0424190 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
GN Hearing	REMOTE CONTROL	RC-3,REMOTE CONTROL,GEN	21237900	RC-3	57885	570829 600003 73J	TBD