

EC - Declaration of Conformity

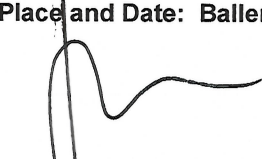
Manufacturer:	GN Hearing A/S Lautrupbjerg 7 DK-2750 Ballerup Denmark												
Conformity Assessment Procedure:	Annex VII of Medical Device Directive (MDD) 93/42/EEC Annex III of Radio Equipment Directive (RED) 2014/53/EU												
Identification of Notified Body (RED):	American Certification Body Inc. 6731 Whittier Ave, Suite C110, McLean, VA 22101, USA Notified Body EC Code No. 1588												
Identification of the EC-certificate (RED):	ACB Certificate No. ATCB021862												
Identification of the Device:	<table border="0"> <tr> <td style="vertical-align: top;">Category:</td> <td>Accessory</td> </tr> <tr> <td style="vertical-align: top;">Type:</td> <td>Wireless Bluetooth Bridge</td> </tr> <tr> <td style="vertical-align: top;">Brand:</td> <td>ReSound</td> </tr> <tr> <td style="vertical-align: top;">Model:</td> <td>Phone Clip+ BTB-2</td> </tr> <tr> <td style="vertical-align: top;">GMDN:</td> <td>57886</td> </tr> <tr> <td style="vertical-align: top;">Revision:</td> <td>214</td> </tr> </table>	Category:	Accessory	Type:	Wireless Bluetooth Bridge	Brand:	ReSound	Model:	Phone Clip+ BTB-2	GMDN:	57886	Revision:	214
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Revision:	214												
Declaration of Conformity expiry date:	31-12-2019												
Classification of the Device (MDD):	Class I, Rules 1 and 12, MDD 93/42/EEC												

Applied standards and normative standards:

MDD: EN 60601-1-2:2007/AC:2010, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 14971:2012
RED: Health & Safety: EN 60950-1:2006 + A2:2013, EN/(IEC) 62479:2010;
 EMC: EN 301 489-17 V3.2.0, EN 301 489-1 V2.2.0;
 Spectrum: EN 300 328 V2.1.1

We, the manufacturer hereby declare that the above-mentioned devices comply with the relevant provisions of the EU Council Directive 93/42/EEC (MDD) Annex I - Essential Requirements and the relevant provisions of the EU Council Directive 2014/53/EU (RED) Article 3 - Essential Requirements and their relevant transpositions into national laws of the Member States in which the above-mentioned devices are distributed.

Place and Date: Ballerup, 24-05-2018


Helen Ljungdahl Round
 Senior Vice President
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 GN Hearing A/S


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