

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 II of Radio Equipment Directive (RED)

2014/53/EU

Identification of the Device:

Category:

Accessory

Type:

Wireless Remote Control

Brand:

ReSound

Model:

Remote Control 2

RC-2

GMDN:

57885

Revision:

221

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 Global Marketing

GN Hearing A/S

Lars Hagander
Vice President
Corporate Quality

GN Hearing A/S