

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 and
Telecommunications Terminal Equipment
(R&TTE) 1999/5/EC

Identification of the Device:**Category:**

Accessory

Type:

Wireless remote control

Brand:

Beltone

Model:

Direct Family
Remote Control 2
RC-2

Revision:

Report No. 221

Classification of the Device (MDD):

Class I, Rules 1 and 12, MDD 93/42/EEC

Applied standards and normative standards:

MDD: EN/(IEC) 60601-1-2:2007 (3rd edition)

ISO 10993-5:2009, ISO 10993-10:2009, ISO 14971:2007

R&TTE: EN/(IEC) 60950-1:2006, EN/(IEC) 62479:2010 (Health & Safety)

EN/(IEC) 301 489-17 V2.1.1:2009 (EMC)

EN/(IEC) 300 328 V1.7.1:2006 (Spectrum)

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 essential requirements and other relevant requirements of the R&TTE Directive 1999/5/EC and their relevant transpositions into national laws of the Member States in which the above mentioned medical devices are distributed.

Place and Date: Ballerup, 19 June 2013



Gian Carlo Sciuchetti

Senior Vice President
Global Marketing
GN ReSound A/S



Lars Hagander

Vice President
Corporate Quality
GN ReSound A/S

Doc. ref. 00066490