

## 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 Bluetooth bridge  
**Brand:** Beltone  
**Model:** Direct Family  
Phone Link 2

**GMDN:** 57886

**Revision:** Report No. 214


**Classification of the Device (MDD):** Class I, Rules 1 and 12, MDD 93/42/EEC

**Applied standards and normative standards:**

MDD: The parts of EN/(IEC) 60601-1-2:2001+A1 not related to the AC/DC adapters, ISO 10993-5:2009, ISO 10993-10:2009, ISO 14971:2007  
R&TTE: EN/(IEC) 60950-1:2006, EN/(IEC) 62311:2008 (Health & Safety)  
EN/(IEC) 301 489-17 V2.1.1:2009 (EMC)  
EN/(IEC) 300 440-2 V1.3.1:2009 (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, 3 December 2012



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