

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 stationary audio streamer
Brand: Beltone
Model: Direct Family
TV Link 2
SAS-3

Revision: Report No. 223

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, 16 August 2013


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