

EC – Declaration of Conformity

Manufacturer: Beltone A/S
Lautrupbjerg 7
DK-2750 Ballerup
Denmark

Conformity Assessment Procedure: Annex II of Medical Device Directive (MDD) 93/42/EEC
Annex III of Radio and Telecommunications Terminal Equipment (R&TTE) 1999/5/EC

Identification of Notified Body (MDD): DQS Medizinprodukte GmbH
August-Schanz-Str. 21,
D-60433 Frankfurt am Main, Germany
Notified Body EC Code No. 0297

Identification of EC-certificate (MDD): DQS Certificate No. 283130 MR2

Identification of the Device: **Category:** Hearing Aid
Type: Behind-The-Ear
Brand: Beltone
Model: Promise Family
PSE1785-DLW, PSE1785-DGLW
PSE985-DLW, PSE985-DGLW

GMDN code: 34671

Revision: Report No. 210

Declaration of Conformity expiry date: 2016-12-31

Classification of the Device (MDD): Class IIa, Rule 9, MDD 93/42/EEC

Applied standards and normative standards:
US: ANSI 63.19-2006
MDD: IEC 60118-0:83+A1:94, IEC 60118-7:2005, IEC 60118-13:2004,
ISO 10993-5:2009, ISO 10993-10:2010, ISO 14971:2007
R&TTE: EN/(IEC) 60601-1-1:2001, EN/(IEC) 62311:2008 (Health & Safety)
EN/(IEC) 60601-1-2:2001+A1, EN/(IEC) 301 489-17 2.1.1:2009 (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, 12 September 2012



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