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 PSE1764-DRW, PSE1764-DRPW, PSE1764-DRSW PSE1763-DRW, PSE1763-DRPW, PSE1763-DRSW PSE964-DRW, PSE964-DRPW, PSE964-DRSW PSE963-DRW, PSE963-DRPW, PSE963-DRSW
	GMDN code:	47169
	Revision:	Report No. 208
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, 30 August 2012

Gian Carlo Sciuchetti
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Corporate Quality
GN ReSound A/S

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