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:	In-The-Ear
	Brand:	Beltone
	Model:	Promise Family PSE635-W, PSE635-DW, PSE635-DPW, PSE635-PW, PSE635-MW, PSE635-MPW, PSE635-MUW
	GMDN code:	41209
	Revision:	Report No. 216
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, 7 March 2013

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