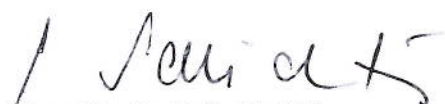


EC – Declaration of Conformity

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 PSE645-W, PSE645-DW, PSE645-DPW, PSE645-PW
	GMDN code: 34672
	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



Gian Carlo Sciuchetti
Senior Vice President
Global Marketing
GN ReSound A/S



Lars Hagander
Vice President
Corporate Quality
GN ReSound A/S

Doc. ref. 00066490