

## EC – Declaration of Conformity

<b>Manufacturer:</b>	Beltone A/S Lautrupbjerg 7 DK-2750 Ballerup Denmark
<b>Conformity Assessment Procedure:</b>	Annex II of Medical Device Directive (MDD) 93/42/EEC Annex III of Radio and Telecommunications Terminal Equipment (R&TTE) 1999/5/EC
<b>Identification of Notified Body (MDD):</b>	DQS GmbH Deutsche Gesellschaft zur Zertifizierung von Managementsystemen Notified Body EC Code No. 0297
<b>Identification of EC-certificate (MDD):</b>	DQS Certificate No. 283130 MR2
<b>Identification of the Device:</b>	<b>Category:</b> Hearing Aid <b>Type:</b> Behind-The-Ear <b>Brand:</b> Beltone <b>Model:</b> True Family TRU1778DW, TRU1778DW HPG TRU978DW, TRU978DW HPG TRU678DW, TRU678DW HPG
	<b>Revision:</b> Report No. 175
<b>Classification of the Device (MDD):</b>	Class IIa, Rule 9, MDD 93/42/EEC
<b>Applied standards and normative standards:</b>	
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 10993-10:2009, 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, 23 August 2011



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Doc. ref. 00066490