EC – Declaration of Conformity

Manufacturer:		Beltone A/S Lautrupbjerg 7 DK-2750 Ballerup Denmark
Conformity Assessment Procedure		Annex II of the Medical Device Directive 93/42/EEC
Identification of Notified Body		DQS Medizinprodukte GmbH August-Schanz-Str. 21, D-60433 Frankfurt am Main, Germany Notified Body EC Code No. 0297
Identification of the Device	**Category:**	Accessory
	Type:	Software application
	Brand:	Beltone
	Model:	Apps Family Beltone SmartRemote
	Revision:	Report No. 215
Classification of the Device:		Class I, Rule 12, MDD 93/42/EEC

Applied standards and normative standards:
ISO 14971:2007

We, the manufacturer hereby declare that the above-mentioned devices comply with the relevant provisions of the EU Council Directive 93/42/EEC, Annex I - Essential Requirements and its relevant transpositions into national laws of the Member States in which the above-mentioned medical devices are distributed.

Place and Date: Ballerup, 20 December 2012

Gian Carlo Sciuchetti
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