EC – Declaration of Conformity

Manufacturer:		GN Hearing A/S Lautrupbjerg 7 DK-2750 Ballerup Denmark
Conformity Assessment Procedure:		Annex VII of Medical Device Directive (MDD) 93/42/EEC Annex III of Radio and Telecommunications Terminal Equipment (R&TTE) 1999/5/EC
Identification of the Device:	**Category:**	Accessory
	Type:	Assistive Listening Device
	Brand:	Beltone
	Model:	Direct Family myPAL Pro SM-2P
	GMDN code:	57886
	Revision:	Report No. 296
Classification of the Device:		Class I, Rule 12, MDD 93/42/EEC

Applied standards and normative standards:
MDD: ISO 10993-5:2009, ISO 10993-10:2010, ISO 14971:2012
R&TTE: EN/(IEC) 60950-1:2006, EN/(IEC) 62479:2010 (Health & Safety)
EN 301 489-17 2.2.1 (EMC), EN 300-328 V1.9.1 (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, 26 February 2016

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