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 Equipment Directive (RED) 2014/53/EU
Identification of the Device:	**Category:**	Accessory
	Type:	Assistive Listening Device
	Brand:	GN Hearing
	Model:	Micro Mic SM-2M
	Revision:	Report No. 296
Classification of the Device (MDD):		Class I, Rules 1 and 12, MDD 93/42/EEC

Applied standards and normative standards:

MDD: EN 60601-1-2:2007/ AC:2010, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 14971:2012

RED: Health & Safety: EN 60950-1:2006 + A2:2013, EN/(IEC) 62479:2010;
EMC: EN 301 489-17 V3.2.0, EN 301 489-1 V2.2.0;
Spectrum: EN 300 328 V2.1.1.

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 RED 2014/53/EU 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 October 2017

Helen Ljungdahl Round
Senior Vice President
Global Marketing
GN Hearing A/S

Lars Hagander
Vice President
Corporate Quality
GN Hearing A/S

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