

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 Notified Body (RED): American Certification Body Inc.
6731 Whittier Ave, Suite C110, McLean,
VA 22101, USA
Notified Body EC Code No. 1588

Identification of the EC-certificate (RED): ACB Certificate No. ACTB021865

Identification of the Device:

Category:	Accessory
Type:	Assistive Listening Device
Brand:	ReSound
Model:	Micro Mic SM-2M
GMDN:	57886
Revision:	296

Declaration of Conformity expiry date: 31-12-2019

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, EN 300 422-4 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 relevant provisions of the EU Council Directive 2014/53/EU (RED) Article 3 - Essential Requirements and their relevant transpositions into national laws of the Member States in which the above-mentioned devices are distributed.

Place and Date: Ballerup, 24-05-2018


Helen Ljungdahl Round
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Global Marketing
GN Hearing A/S


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GN Hearing A/S