

## EC – Declaration of Conformity

**Manufacturer:**

Beltone 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:**

Beltone

**Model:**

myPAL Micro  
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



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Doc. ref. 00066490