

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:

Wireless Bluetooth Bridge

Brand:

Beltone

Model:

Direct
Phone Link 2
BTB-2

Revision:

Report No. 214

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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Lars Hagander
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