

Document No.: BE1221\_039DOC001

## **EC DECLARATION OF CONFORMITY**

The undersigned, representing the following manufacturer.

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Herewith declares that the products

Type of equipment	Brand name			Standard used to prove conformity. Table 2.
Wireless Bed Shaker	Bellman Vibio Bluetooth Bed Shaker	BE1221	C, D, E, F	3,4, 5, 8, 9, 10, 11

Is in conformity with the provisions of the following EEC/EU directives and applicable essential requirements set out in related directives.

	Reference No:	Title:
A	2014/35/EU	Low Voltage Directive (LVD)
В	2014/30/EU	Electromagnetic Compatibility (EMC Directive)
C	2014/53/EU	Radio Equipment Directive (RED)
D	93/42/EEC	Medical Devices Directive (MDD)
E	2015/863/EU	Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive)
F	EU Regulation (EC) No 1907/2006	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

## Table 1. List of EC directives

This declaration of conformity is issued under the sole responsibility of the manufacturer, and that related applicable harmonized standards and/or technical specifications referenced overleaf have been applied.

Bellman & Symfon AB declares herby that the products above conform to applicable requirements in the Swedish Act (1993:584), Ordinance (SFS 1993:876), and regulation, LVFS 2003:11 regarding medical device provision form Medical Products Agency MPA - Läkemedelsverket.

Guangzhou China; Jul. 21, 2019

CTO, Bellman & Symfon AB

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Relevant harmonised standards used or specifications in relation to conformity:

No.	Standard No.	Issue	Title		
1	EN 55032 + AC	2016	Electromagnetic compatibility of multimedia equipment — Emission requirements		
2	EN 55024 + A1 + A2	2015	Information technology equipment – Immunity characteristics. Limits and methods of measurement + Amendments 1 + Amendment 2		
3	EN 60601-1 + A1	2013	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance		
4	EN 60601-1-2	2015	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests		
5	EN 60950-1 + A11 + A1 + A12 + A2	2013	Information technology equipment - Safety - Part 1: General requirements		
6	EN 61000-3-2	2014	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)		
7	EN 61000-3-3	2013	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current <= 16 A per phase and not subject to conditional connection		
8	EN 300 328 V2.1.1	2016	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU		
9	EN 62479	2010	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz) (IEC 62479:2010, modified); German version EN 62479:2010		
10	EN 301 489-1 V2.2.0	2017	Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU		
11	EN 301 489-17 V3.2.0	2017	Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU		
12	EN 55014-1 + A2	2011	Electromagnetic compatibility. Requirements for household appliances, electric tools and similar apparatus. Emission		

Table 2. List of standards

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