

EU DECLARATION OF CONFORMITY

Standalone Family Medical Device and Medical Device System:

BE1221-P02: The intended purpose of the Vibio Bed Shaker is to awake and alert deaf and hard of hearing people of a set alarm.

BE1370-C: The intended purpose of the alarm clock is to awake and alert deaf and hard of hearing people of a set alarm.

The undersigned, representing the following manufacturer.

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Herewith declares that the products are in conformity with the provisions of the EU/EC regulations, directives and applicable essential requirements stated in Table 1.

Table 1. List of products

Type of equipment	Product name	REF No.	MDR risk class, Annex VIII chapter 6, rule applied	Conformity with the regulations and directives in Table 2.	Harmonized Standards* in Table 3 used to prove conformity	Basic UDI-DI
Medical Device	Vibio Bed Shaker	BE1221-P02**	Class I, Rule 13	A, B, G, H, I, J	1, 2, 3, 6, 9	733164600873
Medical Device System	Alarm Clock Pro	BE1370-C	Class I, Rule 13	A, C, D, G, H, I, J	10, 11, 12, 13, 14	733164600975

*Standards harmonized for medical devices, as declared per (EU) 2017/745, are listed in a separate Harmonised Standards List.

**BE1221-P02 Vibio Bed Shaker requires the smart device application BE9620-And or BE9620-iOS to be used as intended, see their separate Declaration of Conformity "Standalone_019DOC".

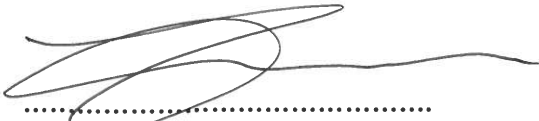
Table 2. List of EU/EC regulations and directives

	Reference No.	Title
A	(EU) 2017/745	Medical Device Regulation (MDR)
B	2014/53/EU	Radio Equipment Directive (RED)
C	2014/35/EU	Low Voltage Directive (LVD)
D	2014/30/EU	Electromagnetic Compatibility Directive (EMC)
E	(EU) 2023/988	General Product Safety Regulation (GPSR)
F	(EU) No 305/2011	Construction Products Regulation (CPR)
G	2011/65/EU + (EU) 2015/863	Restriction of the use of certain hazardous substances in electrical and electronic equipment Directive (RoHS)
H	(EC) No 1907/2006	Registration, Evaluation, Authorization and Restriction of Chemicals Regulation (REACH)
I	2012/19/EU	Waste Electrical and Electronic Equipment Directive (WEEE)
J	(EU) 2023/1542	Battery regulation

Document No.: Standalone_018DOC 4.0

This declaration of conformity is issued under the sole responsibility of Bellman & Symfon Group AB.

Gothenburg, Sweden. Date: 2026-06-26



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Jonas Pehrsson
CTO, Bellman & Symfon Group AB

Table 3. List of harmonized standards

Standard number	EU directive (Table 2)		Harmonized standard	
1	B	2014/53/EU (RED)	EN 62368-1:2014 (EN 62368-1:2014+A11:2017)	Audio/video, information and communication technology equipment Part 1: Safety requirements
2	B	2014/53/EU (RED)	EN 301 489-1 V1.9.2 (EN 301 489-1 V2.2.3:2019)	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
3	B	2014/53/EU (RED)	EN 300 328 V2.1.1	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
4	B	2014/53/EU (RED)	EN 300 220-1 V3.1.1	Short Range Devices (SRD) operating in the frequency range 25 MHz to 1 000 MHz; Part 1: Technical characteristics and methods of measurement
5	B	2014/53/EU (RED)	EN 300 220-2 V3.1.1	Short Range Devices (SRD) operating in the frequency range 25 MHz to 1 000 MHz; Part 2: Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU for non specific radio equipment
6	B	2014/53/EU (RED)	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
7	B	2014/53/EU (RED)	EN 301 489-1 V1.9.2	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
8	B	2014/53/EU (RED)	EN 301 489-3 V2.1.1	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz; Harmonised Standard for ElectroMagnetic Compatibility.
9	B	2014/53/EU (RED)	EN 301 489-17 V3.2.4:2020	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
10	C	2014/35/EU (LVD)	EN 62368-1:2014, EN 62368-1:2014/AC:2015 (EN 62368-1:2014+A11:2017)	Audio/video, information and communication technology equipment Part 1: Safety requirements
11	D	2014/30/EU (EMC)	EN 55035:2017 EN 55035:2017/A11:2020	Electromagnetic compatibility of multimedia equipment - Immunity requirements
12	D	2014/30/EU (EMC)	EN 55032:2015, EN 55032:2015/A11:2020	Electromagnetic compatibility of multimedia equipment — Emission requirements

13	D	2014/30/EU (EMC)	EN 61000-3-2:2014 (EN 61000-3-2:2019)	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
14	D	2014/30/EU (EMC)	EN 61000-3-3:2013 (EN 61000-3-3:2013/A1:2019)	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
15	D	2014/30/EU (EMC)	EN 61000-3-2:2014	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
16	D	2014/30/EU (EMC)	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