Bellman & Symfon®
DESIGN FOR EARS

EU DECLARATION OF CONFORMITY

Standalone family Medical Device Accessories:

The intended purpose of the Vibio Bed Shaker 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.	Basic UDI-DI
Medical Device Accessory	Vibio Bed Shaker App	BE9620-And	Class I, Rule 13	A	73316460076Z
Medical Device Accessory	Vibio Bed Shaker App	BE9620-iOS	Class I, Rule 13	A	73316460076Z

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

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

Gothenburg, Sweden. Date: 2024-05-25

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David Rosén
CEO, Bellman & Symfon Group AB