

Document No.: Alerting\_018DOC 1.0

## **EU DECLARATION OF CONFORMITY**

## Alerting Mobile Application Medical Device Accessories:

The intended purpose of the Visit alerting system is to alert deaf and hard of hearing people of important signals in their home.

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 Accessories	Bellman Visit Legacy App	BE9600-And	Class I, Rule 13	A	73316460036R
Medical Device Accessories	Bellman Visit Legacy App	BE9600-iOS	Class I, Rule 13	A	73316460036R
Medical Device Accessories	Bellman Visit App	BE9610-And	Class I, Rule 13	A	73316460036R
Medical Device Accessories	Bellman Visit App	BE9610-iOS	Class I, Rule 13	A	73316460036R

Table 2. List of EU/EC regulations and directives

	Reference No.	Title
A	(EU) 2017/745	Medical Device Regulation (MDR)
В	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)	Restriction of the use of certain hazardous substances
G	2015/863	in electrical and electronic equipment Directive (RoHS)
Н	(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



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

Gothenburg, Sweden. Date: 2021-05-25

David Rosén

CEO, Bellman & Symfon Group AB