

EU DECLARATION OF CONFORMITY

Alerting TxRx Medical Devices:

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	Visit Door Transmitter	BE1411-868	Class I, Rule 13	A, B, G, H, I, J	73316460016M
Medical Device	Visit Pushbutton Transmitter	BE1420-868	Class I, Rule 13	A, B, G, H, I, J	73316460016M
Medical Device	Visit Telephone Transmitter	BE1431-868	Class I, Rule 13	A, B, G, H, I, J	73316460016M
Medical Device	Visit Mobile Phone Transceiver	BE1433	Class I, Rule 13	A, B, G, H, I, J	73316460016M
Medical Device	Visit Flash Receiver	BE1441-868	Class I, Rule 13	A, B, G, H, I	73316460016M
Medical Device	Visit Flash Receiver	BE1442-868	Class I, Rule 13	A, B, G, H, I, J	73316460016M
Medical Device	Visit Portable Receiver	BE1450-868	Class I, Rule 13	A, B, G, H, I, J	73316460016M
Medical Device	Visit Pager Receiver	BE1470-868	Class I, Rule 13	A, B, G, H, I, J	73316460016M
Medical Device	Visit Baby Monitor	BE1491-868	Class I, Rule 13	A, B, G, H, I, J	73316460016M

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

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

Gothenburg, Sweden. Date: 2025-05-07



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David Rosén
CEO, Bellman & Symfon Group AB