

EU DECLARATION OF CONFORMITY

Audio family Medical Device Accessories:

The intended purpose of the audio product family is to amplify the volume and improve the speech intelligibility during conversations and TV-listening. It can also be used with other sound sources.

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

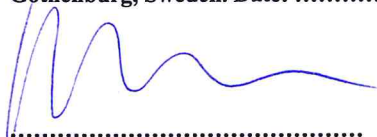
Type of equipment	Product name	REF No.	MDR risk class, Annex VIII chapter 6, rule applied	Conformity with the regulations and directives in Table 2.	Basic UDI-DI
Medical Device Accessory	Neck Loop Long Cable	BE9159-P02	Class I, Rule 13	A, C, D, G, H, I	73316460116Q
Medical Device Accessory	Neck Loop Short Cable	BE9161-P02	Class I, Rule 13	A, C, D, G, H, I	73316460116Q
Medical Device Accessory	Headphones	BE9122-P02	Class I, Rule 13	A, C, D, G, H, I	73316460126S
Medical Device Accessory	Earphones	BE9124-P02	Class I, Rule 13	A, C, D, G, H, I	73316460126S
Medical Device Accessory	In-ear Headset	BE9229-P02	Class I, Rule 13	A, C, D, G, H, I	73316460126S
Medical Device Accessory	On-ear Headset	BE9233-P02	Class I, Rule 13	A, C, D, G, H, I	73316460126S
Medical Device Accessory	External Microphone	BE9136-P02	Class I, Rule 13	A, C, D, G, H, I	73316460126S

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: 2025-06-02



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David Rosén
CEO, Bellman & Symfon Group AB