Bellman & Symfon®
DESIGN FOR EARS

EU DECLARATION OF CONFORMITY

Audio family Medical Device Systems:

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.

Name:	**Bellman & Symfon Group AB**
SRN:	**SE-MF-000046749**
Address:	**Södra Långebergsgatan 30, 436 32 Askim, Sweden**
Telephone no:	**+46 31 68 28 20** Telefax no: **+46 31 68 28 90**

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 System	Maxi Pro Personal Amplifier	BE2021-C	Class I, Rule 13	A, B, C, D, G, H, I, J	73316460136U
Medical Device System	Maxi Pro TV Listening System	BE8054-C	Class I, Rule 13	A, B, C, G, H, I, J	73316460136U

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: 2025-05-15

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David Rosén
CEO, Bellman & Symfon Group AB