Document No.: Audio_032DOC 1.0

Bellman & Symfon®
DESIGN FOR EARS

EU DECLARATION OF CONFORMITY

Audio family Medical Device:

Intended purpose 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

Table 1. List of products

Type of equipment	Product name	Model	MDR risk class, Annex VIII chapter 6, rule applied	Conformity with the directives in Table 2.	Standard used to prove conformity. Table 3.	Basic UDI-DI
Medical Device	Maxi Personal Amplifier	BE2020	Class I, Rule 13	A, C, D, F, G, H, I	1,2,3,4,5,6,7,8,9,12,13,14,15,16	73316460106N
Medical Device	Maxi Pro Personal Amplifier	BE2021	Class I, Rule 13	A, B, F, G, H, I	1,2,3,4,5,6,7,8,9,10,11,12,17,19	73316460106N
Medical Device	Maxi Pro Television streamer	BE2022	Class I, Rule 13	A, B, F, G, H, I	1,2,3,4,5,6,7,8,9,10,11,12,17,19	73316460106N
Medical Device	Mino Personal Amplifier	BE2030	Class I, Rule 13	A, C, E, F, G, H, I	1,2,3,4,5,6,7,8,9, 12,13,14,15,16	73316460106N
Medical Device	Domino Pro Rx	BE2210	Class I, Rule 13	A, B, F, G, H, I	1,2,3,4,5,6,7,8,9,10,11,12,17,19	73316460106N
Medical Device	Domino Pro Tx	BE2230	Class I, Rule 13	A, B, F, G, H, I	1,2,3,4,5,6,7,8,9,10,11, 12,17,19	73316460106N

Is in conformity with the provisions of the following EEC/EC/EU regulations, directives and applicable essential requirements set out in related directives.

Table 2. List of EC directives

	Reference No.	Title
A	EU 2017/745	Medical Device Regulation (MDR)
B	2014/53/EU	Radio Equipment Directive (RED)
C	2014/30/EU	Electromagnetic Compatibility (EMC)
D	2001/95/EC	General product safety (GSPD)
E	2014/35/EU	Low voltage (LVD)
F	2011/65/EU	Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
G	(EC) No 1907/2006	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
H	2012/19/EU	Waste Electrical and Electronic Equipment Directive (WEEE)
I	2006/66/EC	Batteries and accumulators and waste batteries and accumulators (Battery Directive)

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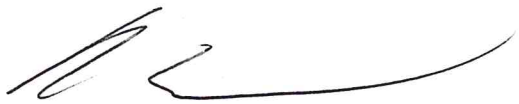
This declaration of conformity is issued under the sole responsibility of Bellman & Symfon Group AB.
The devices covered by the present EU declaration is in conformity with RED and with the (EU) MDR 2017/745 and with the applicable requirements regarding medical device provision from Medical Products Agency MPA – Läkemedelsverket, and any other applicable directives and regulations as indicated.

Goteborg Sweden; Dec. 10, 2021



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Anders Fogelberg
CEO, Bellman & Symfon Group AB

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Relevant Harmonized standards used or specifications in relation to conformity:

Table 3. List of standards

	Standard Number and edition	Standard Title	Type
1	EN 60601-1-11:2015	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	Safety
2	EN 60601-1:2006	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)	Note 1
3	EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014)	Note 1
4	EN 1041:2008	Information supplied by the manufacturer of medical devices	Labeling
5	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)	Risk
6	EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)	Labeling
7	EN 62304:2006	Medical device software - Software life-cycle processes (IEC 62304:2006) EN 62304:2006/AC:2008	Software
8	EN 62366:2008	Medical devices - Application of usability engineering to medical devices (IEC 62366:2007)	Usability
9	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	QMS
10	EN 300 328 V2.1.1	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU	Radio
11	EN 62479:2010	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz) (IEC 62479:2010, modified); German version EN 62479:2010	Health
12	EN 62368-1:2014/AC:2015+A11:2017	Audio/video, information and communication technology equipment Part 1: Safety requirements	Safety
13	EN 55032:2015 + AC:2016	Electromagnetic compatibility of multimedia equipment — Emission requirements	EMC
14	EN 55035:2017	Electromagnetic compatibility of multimedia equipment - Immunity requirements	EMC
15	EN 61000-3-2:2014	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)	EMC
16	EN 61000-3-3:2013	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current <= 16 A per phase and not subject to conditional connection	EMC
17	EN 301 489-1 V2.2.0:2017 EN 301 489-1 V2.1.1:2019	Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU	EMC
18	EN 301489-3 V2.1.1:2017	Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions or Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz; Harmonized Standard covering the essential requirements of	EMC

19	EN 301 489-17 V3.2.0:2017	Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU	EMC

Note 1:

According to IEC 60601-1-11 Annex A.General Guidance and Rational, clause A.2 Rational for particular clauses and subclauses:
The 60601-1-11 gives room for providing safety through other than the 60601-series for certain products *), instead EN 62368-1 Audio/video, information and communication technology equipment - Part 1: Safety requirements (replacing EN 60950) and its corresponding EMC standards.
*) See extract from standard 60601-1-11 below
"Excluded from the scope are aids without an APPLIED PART, and where according to the INTENDED USE, the safety is fully covered by IEC 60950-1 [8], IEC 60065 [2] or IEC 60335-1 [3]. Examples of such equipment are the following:
– a reading aid with a digital camera and a monitor for enlargement of text for persons with impaired vision could be covered by IEC 60065 and related EMC standards;
– a flashing light to indicate that the phone is ringing for persons with impaired hearing could be covered by IEC 60065 and related EMC standards;
– an amplifier for connection to radio or TV sets with wireless transmission to a BODY-WORN hearing aid could be covered by IEC 60065 and related EMC standards; and
– a can opener for persons with impaired hand/finger motion ability is better covered by IEC 60335-1 and related part-2 and EMC standards.
These types of products are in fact home electronics or household appliances rather than medical equipment, even though they might fall within the regulatory definition of a medical device in some countries. Hence, these products should comply with the relevant standard for such products e.g. IEC 60950-1 for the reading aid, IEC 60065 for the TV sound amplifier and IEC 60335-1 for the can opener. Persons handling such aids are not PATIENTS in the concept of IEC 60601-1 i.e. these persons are not more sensitive/vulnerable than people in general. The "PATIENT" operates these products, but they have in many cases no APPLIED PART.
There is no logical reason to require that a TV sound amplifier or a can opener for home use comply with IEC 60601-1 or with IEC 60601-1-2. Electromagnetic compatibility (EMC) is not more critical for these products than for other generic products and there are no 'medical' APPLIED PARTS.