



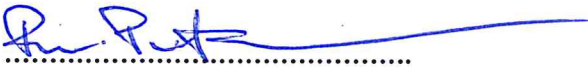
Is in conformity with the provisions of the following EEC/EC/EU regulations, directives and applicable essential requirements set out in related directives.

**Table 2. List of EC directives**

	Reference No.	Title
<b>A</b>	<b>EU 2017/745</b>	<b>Medical Device Regulation (MDR)</b>
<b>B</b>	<b>2014/53/EU</b>	<b>Radio Equipment Directive (RED)</b>
<b>C</b>	<b>(EU) No 305/2011</b>	<b>Construction products (CPR)</b>
<b>D</b>	<b>2011/65/EU+(EU) 2015/863</b>	<b>Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)</b>
<b>E</b>	<b>(EC) No 1907/2006</b>	<b>Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)</b>
<b>F</b>	<b>2012/19/EU</b>	<b>Waste Electrical and Electronic Equipment Directive (WEEE)</b>
<b>G</b>	<b>2006/66/EC</b>	<b>Batteries and accumulators and waste batteries and accumulators (Battery Directive)</b>

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.

Göteborg Sweden. Date: 2024-01-20



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**Fredrik Petersson**  
 CEO, Bellman & Symfon Group AB

**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/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 /A1:2012)	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	EN300 220-1 V3.1.1	Short Range Devices (SRD) operating in frequency range 25 MHz to 1 000 MHz; Part 1: Technical characteristics and methods of measurement.	Radio
11	EN 300 220-2 V3.1.1 EN 300 220-2 V3.2.1	Short Range Devices (SRD) operating in the frequency range 25 MHz to 1 000 MHz; Part 2: Harmonized Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU for nonspecific radio equipment	Radio
12	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
13	EN 62368-1:2014/AC:2015+A11:2017	Audio/video, information and communication technology equipment Part 1: Safety requirements	Safety
14	EN 301 489-1 V2.2.3:2019	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
15	EN 301489-3 V2.1.1:2019	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 articles 3.1(b) of Directive 2014/53/EU	EMC
16	EN14604:2015+AC:2008	Smoke alarm devices	Smoke Alarm
17	EN 50291-1:2018	Electrical apparatus for the detection of carbon monoxide in domestic premises Part1: Test methods and performance requirements.	CO Alarm
18	EN 50291-2:2019	Electrical apparatus for the detection of carbon monoxide in domestic premises Part 2: Electrical apparatus for continuous operation in a fixed	CO Alarm

		installation in recreational vehicles and similar premises including recreational craft. Additional test methods and performance requirements	
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**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.

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