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EU DECLARATION OF CONFORMITY

Alerting Medical Device Accessories:

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.

| Name: | Bellman & Symfon Gr | oup AB | |
|---------------|----------------------|-----------------------------|--|
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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 Accessories | Bed shaker, vibration | BE1270 | Class I, Rule 13 | A, B, C, D, E, F | 1,4,5,6,8,9,11,12,13,1 4,20,21, 23, 24 | 73316460026P |
| Medical Device Accessories | Door mat | BE9026 | Class I, Rule 13 | A, B, C, D, E, F | 4,5,6,8,9,10,11,12,13, 14,20,21,22 | 73316460046T |
| Medical Device Accessories | Magnetic switch | BE9023 | Class I, Rule 13 | A, B, C, D, E, F | 4,5,6,8,9,10,11,12,13, 14,20,21,22 | 73316460046T |
| Medical Device Accessories | Mic long cable | BE9199 | Class I, Rule 13 | A, B, C, D, E, F | 4,5,6,8,9,11,12,13, 14, 20,21 | 73316460046T |
| Medical Device Accessories | Mic short cable | BE9200 | Class I, Rule 13 | A, B, C, D, E, F | 4,5,6,8,9,11,12,13, 14, 20,21 | 73316460046T |
| Medical Device Accessories | Visit Wrist receiver charger | BE1570 | Class I, Rule 13 | A, B, C, D, E, F | 1,4,5,6,8,9,11,12,13, 14, 20,21 | 73316460056V |
| Medical Device Accessories | Visit Pager charger | BE1260 | Class I, Rule 13 | A, B, C, D, E, F | 1,4,5,6,8,9,11,12,13, 14, 20,21 | 73316460056V |
| Medical Device Accessories | Amicus pager charger | BE1251 | Class I, Rule 13 | A, B, C, D, E, F | 1,4,5,6,8,9,11,12,13,1 4,20,23, 24 | 73316460056V |
| Medical Device Accessories | "Bellman Visit" in App Store/Google Play | BE9610 | Class I, Rule 13 | A | 4,5,6,7,8,9 | 73316460036R |
| Medical Device Accessories | "Bellman Visit Legacy" in App Store/Google Play | BE9600 | Class I, Rule 13 | A | 4,5,6,7,8,9 | 73316460036R |

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



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Table 2. List of EC directives

| 1 | Reference No. | Title |
|---|----------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|
| A | EU 2017/745 | Medical Device Regulation (MDR) |
| В | 2014/53/EU | Radio Equipment Directive (RED) |
| C | 2011/65/EU+(EU) 2015/863 | Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) |
| D | (EC) No 1907/2006 | Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) |
| E | 2012/19/EU | Waste Electrical and Electronic Equipment Directive (WEEE) |
| F | 2006/66/EC Batteries and accumulators and waste batteries and accumulators (Batteries) | |

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. 16, 2021

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 | Туре |
|----|--------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 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 |
| 0 | EN 300 328 V2.1.1 EN 300 328 V2.2.2 | 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 | 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 |
| 12 | 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 |
| 3 | 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 |
| 4 | EN 62368- 1:2014/AC:2015+A11:2017 | Audio/video, information and communication technology equipment Part 1: Safety requirements | Safety |
| 5 | EN 55032:2015 + AC:2016 | Electromagnetic compatibility of multimedia equipment — Emission requirements | EMC |
| 6 | EN 55035:2017 | Electromagnetic compatibility of multimedia equipment - Immunity requirements | EMC |
| 7 | EN 55024:2010/A1:2015 | Information technology equipment – Immunity characteristics. Limits and methods of measurement + Amendments 1 + Amendment 2 | EMC |
| 18 | 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 |
| 19 | 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 | EMC |



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| 20 | EN 301 489-1 V2.2.0:2017 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 |
|----|--------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| 21 | 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 |
| 22 | EN 301 489-17 V3.2.0:2017 EN 301 489-17 V3.2.4:2020 | 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 |
| 23 | EN 301 489-52 V1.1.0: 2016 | Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 52: Specific conditions for Cellular Communication Mobile and portable (UE) radio and ancillary equipment; Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU | EMC |
| 24 | EN 301 511 V12.5.1-2017 | Global System for Mobile communications (GSM); Mobile Stations (MS) equipment; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU | GSM Radio |

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.