Bellman & Symfon®
DESIGN FOR EARS

Document No.: AiO_Amicus_001DOC005

# DECLARATION OF CONFORMITY

**The undersigned, representing the following manufacturer.**

| | |
|---|---|
| Name: | **Bellman & Symfon AB** |
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**Herewith declares that the following products:**

| Type of equipment | Brand name | Model | Is in conformity with the following EEC/EU directives. Table 1. | Standard used to prove conformity. Table 2. |
|---|---|---|---|---|
| Transmitter | AIO Transmitter Basic | BE2310 | A, B, C, D | 1, 2, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17. |
| Transmitter | AIO Transmitter Pro | BE2315 | A, B, C, D | 1, 2, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17. |
| Repeater | AIO Repeater | BE2370 | A, B, C, D | 1, 2, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17. |
| Portable Receiver | AIO Pager | BE2340 | A, B, C, D | 1, 2, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17. |
| Portable Receiver Charger | AIO Pager Charger | BE1250 | A, B, C, D | 1, 2, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17. |
| Transmitter | Amicus Transmitter Basic | BE2320 | A, B, C, D | 1, 2, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17. |
| Transmitter | Amicus Transmitter Pro | BE2325 | A, B, C, D | 1, 2, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17. |
| Repeater | Amicus Repeater | BE2371 | A, B, C, D | 1, 2, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17. |
| Portable Receiver | Amicus Pager | BE2350 | A, B, C, D | 1, 2, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17. |
| Portable Receiver Charger | Amicus Pager Charger | BE1251 | A, B, C, D | 1, 2, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17. |

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

| | Reference No: | Title: |
|---|---|---|
| A | 2014/53/EU | Radio Equipment Directive (RED) |
| B | 2014/30/EU | Electromagnetic Compatibility Directive (EMC-directive) |
| C | 93/42/EEC | Medical Device Directive.<br>Risk Class: Class I, Conformity assessment procedure: Annex VII |
| D | 2015/863/EU | RoHS |

Table 1. List of EEC/EU directives

**This declaration of conformity is issued under the sole responsibility of the manufacturer and that related applicable harmonized standards and/or technical specifications referenced overleaf have been applied.**

Bellman & Symfon AB declares herby that the products above conform to applicable requirements in the Swedish Act (1993:584), Ordinance (SFS 1993:876), and regulation, LVFS 2003:11 regarding medical device provision form Medical Products Agency MPA - Läkemedelsverket.

**Guangzhou China, Jul 21 2019**

Vickey 2019.7.21

**Vickey Li,**
**CEO, Bellman & Symfon AB**

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**Relevant harmonised standards used or specifications in relation to conformity:**

| No | Standard No. | Issue | Subject |
|---|---|---|---|
| 1 | EN 55032:2015 + AC:2016 | 2016 | Electromagnetic compatibility of multimedia equipment - Emission Requirements |
| 2 | EN 301 489-1 V2.2.0 (2017-03) | 2017 | Electromagnetic compatibility and radio spectrum matters (ERM). |
| 3 | EN 301 489-3 V2.1.1 (2017-03) | 2017 | Electromagnetic compatibility and radio spectrum matters (ERM). |
| 4 | EN 300 220-1 V3.1.1 (2017-02) | 2017 | Electromagnetic compatibility and radio spectrum matters (ERM); Short Range Devices (SRD). |
| 5 | EN 300 220-2 V3.1.1 (2017-02) | 2017 | Electromagnetic compatibility and radio spectrum matters (ERM); Short Range Devices (SRD). |
| 6 | EN 60950-1:2006 + A11:2009 + A1:2010 + A12:2011 + A2:2013 | 2013 | Information technology equipment. Safety. General requirements. |
| 7 | EN 301 489-52 V1.1.0 (2016-11) | 2016 | Electromagnetic compatibility standard for radio equipment and services. |
| 8 | EN 301 511 V12.5.1 (2017-03) | 2017 | Global System for Mobile communications. |
| 9 | EN ISO 15223-1:2016 | 2016 | Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied -Part 1: General requirements. |
| 10 | EN 60601-1-2:2007 | 2007 | Medical electrical equipment — Part 1-2General requirements for basic safety and essential performance. -Collateral standard: Electromagnetic compatibility — Requirements and tests |
| 11 | EN 62366-1:2015 | 2015 | Medical devices – Part 1: Application of usability engineering to medical devices Application of usability to medical devices. |
| 12 | EN ISO 13485:2012 | 2012 | Medical devices — Quality management systems — Requirements for regulatory purposes. |
| 13 | EN ISO 14971:2012 | 2012 | Medical devices — Application of risk management to medical devices. |
| 14 | EN 1041:2008 | 2008 | Information supplied by the manufacturer of medical devices |
| 15 | TS 151 010-1 V10.5.0 (2013-07) | 2013 | Technical Specification Group GSM/EDGE Radio Access Network Digital cellular telecommunications system Part 1: Conformance specification |
| 16 | EN 60601-1:2006 + A1:2013 | 2013 | Medical electrical equipment Part:1General requirements for basic safety and essential performance. |
| 17 | EN 60601-1-11:2015 | 2015 | Medical electrical equipment Part:1General requirements for basic safety and essential performance. -Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. |

Table 2. List of harmonized standards