Bellman & Symfon®
DESIGN FOR EARS

EC DECLARATION OF CONFORMITY

The undersigned, representing the following manufacturer.

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Herewith declares that the 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.
Co Alarm	Visit Co alarm Transmitter	BE1555	BCDE	1,2,5,6,7,16,17,18,19,20

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

	Reference No:	Title:
A	2014/30/EU	Electromagnetic Compatibility (EMC Directive)
B	2014/53/EU	Radio Equipment Directive (RED)
C	93/42/EEC	Medical Devices Directive (MDD)
D	ROHS(2015/863/EU)	Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive)
E	EU Regulation (EC) No 1907/2006	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

Table 1. List of EC 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; Jun 21st, 2019

Vickey Li

Vickey Li,
CTO, Bellman & Symfon AB

Relevant harmonised standards used or specifications in relation to conformity:

No.	Standard No.	Issue	Title
1	EN 50291-1	2010	Electrical apparatus for the detection of carbon monoxide in domestic premises. Test methods and performance requirements.
2	EN50291-2	2010	Electrical apparatus for the detection of carbon monoxide in domestic premises. Electrical apparatus for continuous operation in a fixed installation in recreational vehicles and similar premises including recreational craft. Additional test methods and performance requirements
3	EN 55032 + AC	2016	Electromagnetic compatibility of multimedia equipment — Emission requirements
4	EN 55024 + A1 + A2	2015	Information technology equipment – Immunity characteristics. Limits and methods of measurement + Amendments 1 + Amendment 2
5	EN 60601-1 + A1, A12	2014	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
6	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
7	EN 60950-1 + A11 + A1 + A12 + A2	2013	Information technology equipment - Safety - Part 1: General requirements
8	EN 61000-3-2	2014	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
9	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
10	EN 61000-4-2 +A1 + A2	2009	Electromagnetic compatibility (EMC) -- Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
11	EN 61000-4-3 +A1 + A2	2010	Electromagnetic compatibility (EMC) -- Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
12	EN 61000-4-4	2012	Electromagnetic compatibility (EMC) -- Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test
13	EN 61000-4-5	2014	Electromagnetic compatibility (EMC) -- Part 4-5: Testing and measurement techniques - Surge immunity test
14	EN 61000-4-6 +AC	2015	Electromagnetic compatibility (EMC) -- Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields
15	EN 61000-4-11	2004	Electromagnetic compatibility (EMC) -- Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests
16	EN300 220-1 V3.1.1	2017-02	Short Range Devices (SRD) operating in frequency range 25 MHz to 1 000 MHz; Part 1: Technical characteristics and methods of measurement.
17	EN300 220-2 V3.2.1	2018-06	Short Range Devices (SRD) operating in frequency range 25 MHz to 1 000 MHz; Part 2: Harmonised Standard for access to radio spectrum for non specific radio equipment
18	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
19	EN 301 489-1 V2.2.1	2019	Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for Electromagnetic Compatibility
20	EN 301 489-3 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; Harmonised Standard covering the essential requirements of articles 3.1(b) of Directive 2014/53/EU
21	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;

			Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
22	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
23	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
24	EN 1041	2008	Information supplied by the manufacturer of medical devices
25	EN ISO 14971	2012	Medical devices — Application of risk management to medical devices

Table 2. List of standards