# DECLARATION OF CONFORMITY
## European Medical Device Directive 93/42/EEC

Manufacturer

**EarlySense Ltd.**

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EC Authorized Representative

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I, the undersigned, hereby declare that the distributed CE marked products, specified in the annexed product list, conform to the product(s) covered by the "CE Marking of Conformity Certificate", reference number 2123743CE01 issued on April 16, 2009 and delivered by *DEKRA Certification* Notified Body Identification Number 0344, in accordance with Annex II of the Council Directive 93/42/EEC of 14 June 1993 and amendments of Directive 2007/47/EC of September 5, 2007, concerning medical devices and in accordance with RoHS Directive 2011/65/EU. The RoHS directive is not covered by *DEKRA* Certification BV.

Revision: 25.0

Date: October 2020

Signature: Matt Johnson

Name Matt Johnson
Position CEO
Company EarlySense Ltd.

Annex: Product list (document identification)

# ANNEX
# PRODUCT LIST

This product list below belongs to the Declaration of Conformity identified by EarlySense, and specifies the CE marked products that EarlySense intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC and its amendments concerning medical devices.

The following list identifies the products by model name.

| **Product name** | **Product Description** | **Classification** | **Serial number/ Manufacturing date** |
|---|---|---|---|
| **EarlySense Central Display Station - Software (1.0S)**<br><br>Modules:<br>"All-in-One" module<br>"Vitals" module<br>"Safety" module | Remote station software (control and display) of EarlySense bed-side data on a central display | According to the Directive Annex IX, Rule 10, the device was classified as a **Class IIb**. | First placed on market – May 2010<br>SW 1.1.9-1 and up<br>Since June 2019 |
| **EarlySense InSight System (model AME-01350-EU)** | Compact patient-monitoring device to allow contactless monitoring from bed and chair sensor | According to the Directive Annex IX, Rule 10, the device was classified as a **Class IIb**. | Start of InSight (part number AME-01350-EU) - May 2019 |
| **EarlySense 2.0**<br><br>Modules:<br>"All-in-One" module<br>"Vitals" module<br>"Safety" module | Patient-monitoring Device to allow contactless monitoring from bed sensor, from oximetry and from chair sensor | According to the Directive Annex IX, Rule 10, the device was classified as a **Class IIb**. | Non RoHs Product:<br>Start: S/N EO2011130101<br>End: S/N EO2003140300<br><br>RoHs compatible<br>Start S/N EO2007140301 |

**Products END OF LIFE:**

| | | | |
|---|---|---|---|
| **EarlySense InSight System (model AME-01340-02 EU)** | Compact patient-monitoring device to allow contactless monitoring from bed and chair sensor | According to the Directive Annex IX, the device was classified as a **Class IIb** | Start from July 2020, following Dekra approval |
| **EarlySense 1.0** | Patient-monitoring Device | According to the Directive Annex IX, the device was classified as a **Class IIb.** | Start: S/N EO1104120702<br>End: S/N EO1104121001<br>(Non-RoHS Product) |
| **EverOn 1.0** | Patient-monitoring Device | According to the Directive Annex IX, the device was classified as a **Class IIa.** | Start: S/N EO1001090101<br>End: S/N EO1001090701<br>(Non-RoHS product) |
| **EarlySense Central Display Station - Software** | Software to allow remote display of EarlySense bed-side data on a central display and to external devices | According to the Directive Annex IX, the device was classified as a **Class IIa.** | SW Ver: 1.0.0.<br>SW Ver.: 1.04 (Effective: Feb. 2011)<br>SW Ver: 1.05 (Effective: June 2011)<br>Last SW Ver:1.0.7 (Effective: July 2011)-END |