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| Title: Declaration of Conformity to EU 2017/745 - Eversense E3 and Eversense 365 CGM Systems | <i>Document #:</i> DDOS-0032 |
| | <i>Revision:</i> 07 |
| | <i>Effective Date:</i> 30 Jan 2026 |
| | <i>Pages:</i> 1 of 4 |

DECLARATION OF CONFORMITY

| PRODUCT |
|---|
| Eversense® E3 Continuous Glucose Monitoring System Eversense® 365 Continuous Glucose Monitoring System |

Eversense E3 Continuous Glucose Monitoring System Components

| Model Name | Model / Finished Good Number | Basic UDI-DI | Intended Purpose |
|--|------------------------------|-------------------|---|
| Eversense E3 Smart Transmitter Kit | FG-3500-XX-XXX | 081749102FG3500T8 | <p>The Eversense E3 CGM System is indicated for continually measuring glucose levels in adults (18 years and older) with diabetes for up to 180 days. The system is indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions.</p> <p>The system is intended to:</p> <ul style="list-style-type: none"> • Provide real-time glucose readings. • Provide glucose trend information. • Provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia). • Aid in the management of diabetes. <p>Historical data from the system can be interpreted to aid in providing therapy adjustments. These adjustments should be based on patterns and trends seen over time. The system is intended for single patient use.</p> |
| Eversense E3 Sensor Kit | FG-4500-XX-XXX | 081749102FG4500TF | |
| Eversense Mobile Application (iOS) | FG-5101-XX-XXX | 081749102FG5101T4 | |
| Eversense Mobile Application (Android) | FG-5301-XX-XXX | 081749102FG5301TE | |
| Eversense Charging Cradle | FG-6501-XX-XXX | 081749102FG6501TX | |

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Eversense 365 Continuous Glucose Monitoring System Components

| Model Name | Model / Finished Good Number | Basic UDI-DI | Intended Purpose |
|-------------------------------------|------------------------------|-------------------|---|
| Eversense 365 Smart Transmitter Kit | FG-3502-XX-XXX | 081749102FG3502TC | <p>The Eversense 365 CGM System is indicated for continually measuring glucose levels for up to 1 year in people (18 years or older) with diabetes. The system is indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions.</p> <p>The system is intended to:</p> <ul style="list-style-type: none"> • Provide real-time glucose readings. • Provide glucose trend information. • Provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia). • Aid in the management of diabetes. <p>Historical data from the system can be interpreted to aid in providing therapy adjustments. These adjustments should be based on patterns and trends seen over time. The system is intended for single patient use.</p> |
| Eversense 365 Sensor Kit | FG-4502-XX-XXX | 081749102FG4502TK | |
| Eversense 365 App (iOS) | FG-5103-XX-XXX | 081749102FG5103T8 | |
| Eversense 365 App (Android) | FG-5303-XX-XXX | 081749102FG5303TJ | |

Accessories to the Eversense E3 and Eversense 365 Continuous Glucose Monitoring Systems

| Model Name | Model / Finished Good Number | Basic UDI-DI | Intended Purpose |
|---|------------------------------|-------------------|--|
| Eversense Insertion Tools Kit | FG-8501-XX-XXX | 081749102FG8501UD | The Eversense Insertion Tool Kit is intended for use by health care providers to insert compatible Eversense sensors under a patient's skin. |
| Eversense Adhesive Patches: - 390-pack - 180-pack - 30-pack, white - 30-pack, clear - 10-pack, white - 10-pack, clear | FG-6400-XX-XXX | 081749102FG6400TQ | The Eversense Adhesive Patches are intended to secure compatible Eversense Smart Transmitters over the sensor site on the patient's skin. |
| Eversense DMS | FG-5200-XX-XXX | 081749102FG5200T7 | The Eversense Data Management System (DMS) is intended for use as an accessory to |

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| Model Name | Model / Finished Good Number | Basic UDI-DI | Intended Purpose |
|-----------------------------|------------------------------|-------------------|--|
| | | | compatible Eversense CGM products. It is a webbased application that may be used to view, analyze, and store glucose information from your Eversense CGM System. |
| Eversense DMS Pro | FG-5800-XX-XXX | 081749102FG5800U5 | The Eversense Data Management System (DMS) Pro is a tool for healthcare professionals to manage and review glucose data of their patients that use the Eversense CGM System. |
| Eversense NOW App (iOS) | FG-5400-XX-XXX | 081749102FG5400TH | The Eversense NOW App is intended to be used as a secondary display to view glucose data and alerts from Eversense CGM users. |
| Eversense NOW App (Android) | FG-5401-XX-XXX | 081749102FG5401TK | |

| MANUFACTURER | | |
|--|---|---|
| Name of company and company SRN | Address | Persons Responsible for Regulatory Compliance |
| Senseonics, Incorporated SRN: US-MF-000001940 | 20451 Seneca Meadows Parkway Germantown, MD 20876-7005 USA | Aneta Modzelewska Sr. Director, Regulatory Sciences Dawit Belete Director, Quality Sciences Vallikannu Somasundaram Sr. Director, Quality Sciences |

| AUTHORIZED REPRESENTATIVE | | |
|---|--|--|
| Name of company and company SRN | Address | Telephone/email |
| Emergo Europe SRN: NL-AR-000000116 | Westervoortsedijk 60 6827 AT, Arnhem The Netherlands | (+31) (0) 70 345 8570 EmergoEurope@ul.com |

| REGISTRATION INFORMATION | | |
|---|---|-------------------------------|
| Notified Body and ID # | CE certificate number | Date CE Marking first applied |
| BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam NB# 2797 | MDR 736295 (Annex IX Chapter II) MDR 736292 (Annex IX Chapter I and III) | June 9, 2022 |

CONFORMITY ASSESSMENT

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| Device risk classification | Route to compliance | Common standards applied |
|---|--|---------------------------------|
| Class III (active implantable devices or their accessories) according to Rule 8 of Annex VIII of Regulation (EU) 2017/745 | Regulation EU 2017/745, Annex IX (Quality Management System and Assessment of Technical Documentation) | None |

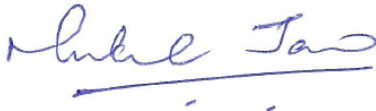
Senseonics, Incorporated declares under its sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC, and Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

This Declaration of Conformity is signed for, and on behalf of, Senseonics, Incorporated by:

COMPANY REPRESENTATIVE: Mukul Jain

TITLE: Chief Operating Officer (COO)

SIGNATURE:



DATE of ISSUE: 30 Jan 2026

PLACE of ISSUE: Senseonics, Incorporated 20451 Seneca Meadows Parkway, Germantown, MD 20876-7005 USA

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