

# PATIENT CONSENT FORM: EVERSENSE® 365 AND EVERSENSE® E3 SENSOR INSERTION/REMOVAL PROCEDURE

**Note to Health Care Provider or Clinic:** By using this SAMPLE consent form, you agree to (i) review and make any revisions that you deem appropriate prior to adopting or incorporating this form into your practice, (ii) take full responsibility over the content and utilization of the consent form with respect to your patients, and (iii) usage is for on-label, clinic based procedures.

Office/Practice Name: _____		
Street Address: _____		
City: _____	State _____	Zip _____
Phone: _____		

**TO THE PATIENT: By reviewing and signing this Consent Form, you are agreeing to receive or undergo the medical procedure described below. Before you provide consent, you have the right to be fully informed about this procedure, including any risks, hazards, and/or side effects involved. Please do not hesitate to discuss the procedure and any questions you may have with your health care provider and his/her staff.**

By my signature below, I consent to the medical procedure described below to be performed by my health care provider (or another designated practitioner), along with assistance from his/her clinical staff, to be performed at the above location. The medical procedure will involve the insertion of an **Eversense 365 or Eversense E3 Continuous Glucose Monitoring (CGM) sensor ("Sensor")**, and/or the removal of a previously-inserted Sensor. The procedure, as well as the Eversense CGM System, has been explained to me completely in terms that I understand.

Specifically, I understand the procedure involves making a small incision (approximately 1cm in width) in my upper arm under local anesthesia, followed by an insertion/removal of the Sensor. The incision will be closed with Steri-Strips and possibly sutures, depending on my healthcare provider's assessment. The closed incision will be covered with a sterile bandage. General risks include possible pain, scarring, bleeding, bruising and/or infection, and any related or consequential conditions or issues. I understand the insertion site will need to stay covered and dry for at least 48 hours after the procedure, and that I will follow the incision care instructions provided by my health care provider. I understand that while the Sensor is intended to be removed at the end of its Sensor life, the Sensor has undergone biocompatibility testing and meets the requirements of a permanent implant, and therefore should not cause a concern if left in place for a longer period.

I understand that I am free to consult with other health care providers about this procedure, and I can refuse any medical treatment at any time prior to its performance. I am aware that the Sensor is designed to function as described in the user guide, though differences in product performance and clinical outcomes may exist between individuals. As applicable, I authorize: (i) a health care provider-in-training to participate in my care; (ii) a representative from a medical device company to be present at the procedure (for education and training); (iii) medical videography/photography to be utilized for virtual procedure support, medical, scientific, or educational purposes, provided my identity is not revealed in any way; and (iv) a health care provider to use and store my information as required to perform the procedure and any follow-up clinical care or questions and share my health information with other health care providers or medical device company representatives necessary to support my clinical care.

## For sensor insertion:

Sensor Type (check one):  Eversense E3  Eversense 365

Sensor Serial Number: \_\_\_\_\_

Sensor Use by Date: \_\_\_\_\_

I have read (or had read to me) and understand the above information, and consent to the procedure.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Name of Patient: \_\_\_\_\_ Patient DOB: \_\_\_\_\_

Name of Patient Representative: (if signed for Patient above) \_\_\_\_\_

Witness Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Witness Name: \_\_\_\_\_

I have explained the information contained in this document to the patient (and/or authorized patient representative). It is my opinion that the person granting consent has fully understood all subjects discussed.

Health Care Provider Signature: \_\_\_\_\_

Name: \_\_\_\_\_