

December 03, 2021

Subject: FCC ID location for FCC ID No: OH2BLEGST1

To whom it may concern:

Medtronic MiniMed requests review of our proposal for FCC Identification labeling pursuant to 47 CFR § 2.925 and 2.926 for the Simplera Sensor.

The Simplera Sensor device is a small body worn glucose sensor designed to aid in the monitoring of interstitial glucose levels in people with diabetes. The device measures 2.6 cm by 2.6 cm. The device is a disposal medical device, worn for seven days and is only available via prescription under the care of a licensed physician.

The Simplera Sensor medical device is worn directly attached to the skin, affixed via an adhesive patch. The primary placement site is the back of the upper arm driven by accuracy and discreteness. The device uses a monolithic housing with no compartments. Simplera Sensor device is intended to provide patients with convenient access to real time glucose levels, and thus discreteness is a key product attribute. For this reason, there are no markings on the face of the device.



The Simplera Sensor device is placed in a separate housing or “Serter” from the factory during which time the device is deactivated. The “Serter” is used by the patient to attach the Simplera Sensor onto the skin.

Medtronic MiniMed proposes to include the FCC ID on the Serter label, which is visible to the user.

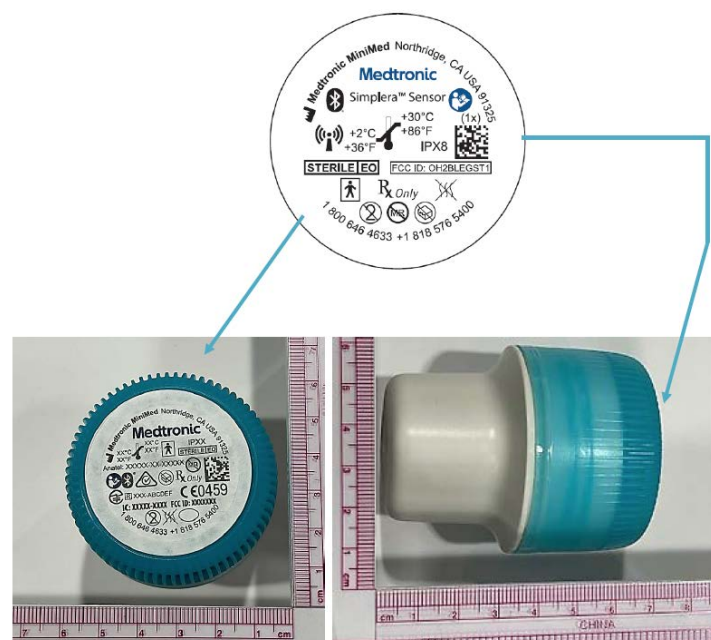


Photo of Serter Showing Proposed FCC ID Placement.

The serter is an integral part of the medical device and is often retained by the patient post sensor application to aid in pairing the device to other components of the system. The FCC ID and other required labeling is also included in the Instructions for Use (User Manual), which accompanies the Simplera Sensor device in the customer packaging.

Given the small size, body worn nature, and discreteness of the sensor Medtronic believes the Serter portion of the medical device as well as the IFU are the best locations for the FCC ID, and otherwise meets the requirements of KDB 784748 D01 section 3 for small devices.

Sincerely,

A handwritten signature in black ink, appearing to read "Mahtab Moberg", is positioned above the printed name and title.

Mahtab Moberg
Sr. Manager, EMC/Safety/ Verification Engineering
Medtronic MiniMed, Inc.