EU MDR Declaration of Conformity (DoC)

Manufacturer:	Medtronic MiniMed 18000 Devonshire Street Northridge, CA 91325 USA
Manufacturer SRN:	US-MF-000023100
Authorized Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Authorized Representative SRN:	NL-AR-000006050
Notified Body:	GMED Notified Body number: 0459 1 rue Gaston Boissier 75015 PARIS FRANCE
Conformity Assessment Certificate(s):	N° 39285 rev. 1
Conformity Assessment Procedure:	MDR 2017/745 Medical Device Regulations Annex IX; Chapter I and III
Risk Class:	IIb
Classification Rule:	Rule 10

Intended Purpose:

The Simplera™ sensor is intended to communicate with the Simplera™ app to provide glucose information for diabetes management. The sensor is designed to replace fingerstick blood glucose (BG) readings for diabetes treatment decisions. The Simplera™ sensor is part of a personal continuous glucose monitoring (CGM) system.
The Simplera™ sensor is intended for single-patient, single-use only. All components of the Simplera™ sensor are disposable. The sensor is pre-loaded into the disposable serter.
The Simplera™ sensor is indicated for the management of diabetes in persons ages 2 years and older.

The Instinct sensor is a single-patient, single-use component of a personal continuous glucose monitoring (CGM) system. It is intended to communicate via Bluetooth Low Energy (BLE) with a compatible Medtronic insulin pump system to provide glucose information for diabetes management. It calculates glucose concentrations based on collected signals from the interstitial fluid and transmits glucose and device data to the networked device. The sensor is designed to replace fingerstick blood glucose (BG) readings for diabetes treatment decisions.
The Instinct sensor is indicated for the management of diabetes in persons ages 2 years and older

Statement:

We, Medtronic MiniMed, hereby declare under our sole responsibility that the product(s) specified herein conform to EU Medical Device Regulation 2017/745 and relevant Union Legislation that provides for the issuing of an EU Declaration of Conformity.

Other Union Legislation(s):

Union Legislation	Applicable Declaration of Conformity Document Number
RoHS Declaration of Conformity	D00928678
Radio Equipment Directive (RE-D) Declaration of Conformity (DoC)	D00780934

Place: Northridge, CA

Name: Mayra Rios

Title: Regulatory Affairs Manager

Signature: Mayra E. Rios

Digitally signed by Mayra E. Rios
Date: 2023.09.21 08:43:57 -04'00'

Date: 9-21-2023

Products Covered

Product Name	Medtronic Product Identifier Model # (with variants-if applicable)	CFN Description	Basic UDI-DI	Optional: Additional nomenclature identifier (e.g. EMDN, GMDN)
Simplera Sensors	MMT-5100JC	SIMPLERA 5PK	0763000B00010377C	44611; Percutaneous Glucose Monitoring System
	MMT-5100JD	SIMPLERA 1PK		
Simplera System Starter Kit	MMT-5101W	KIT SIMPLERA 5PK	0763000B00010377C	44611; Percutaneous Glucose Monitoring System
	MMT-5101WD	KIT SIMPLERA 1PK		
Instinct Sensors	MMT-5120C	INSTINCT 5PK	0763000B00010377C	44611; Percutaneous Glucose Monitoring System
	MMT-5120D	INSTINCT 1PK		

Common Specification(s)

Not Applicable.

The following common specifications were used to demonstrate conformity:

Number	Date of Issue	Title

Revision History

Revision	Date Effective	Description of Change
A	Refer to MAP for effective Date	Initial Release of Document
B		Addition of Instinct Sensors (MMT-510C/D) and Simplera Starter kits (MMT-5101W/WD). Correction of manufacturer address and manufacturer SRN.
C		Correcting a typo error (missing 0) in the BASIC UDI-DI Column