

Certificat/Certificate: N° 39285 rev. 4

Délivré le /Issued on: May 29th, 2024

Certificat délivré à /Certificate issued to: **MEDTRONIC MINIMED**

18000 Devonshire street

NORTHRIDGE, CA 91325 UNITED STATES

SRN: US-MF-000023100

GMED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) d'audit du système de gestion de la qualité et le(s) rapport(s) d'évaluation de la documentation technique associé(s), le cas échéant, référencé(s) P602273 - P605513 - P608064 - P607361, le système de gestion de la qualité est conforme aux dispositions pertinentes du règlement (UE) 2017/745 pour les produits suivants :

GMED certifies that, on the basis of the results listed in the quality management system audit report(s) and the associated technical documentation assessment report, where appropriate, referenced P602273 - P605513 - P608064 - P607361, the quality management system complies with the relevant provisions of the regulation (EU) 2017/745 for the following products:

Système de mesure percutanée du glucose

Percutaneous Glucose Monitoring System

Voir détails sur addendum / See addendum for additional information

Aux fins de la mise sur le marché de dispositifs de classe III et/ou de dispositifs de classe IIb implantables à l'exception des sutures, agrafes, produits d'obturation dentaire, appareils orthodontiques, couronnes dentaires, vis, cales, plaques, guides, broches, clips et dispositifs de connexion, un autre certificat délivré conformément aux dispositions du règlement (UE) 2017/745 est requis.

La validité du présent certificat est conditionnée au respect des obligations qui découlent du système de gestion de la qualité approuvé et de la surveillance effectuée par l'organisme notifié prévue par le règlement. Ce certificat est lié par les conditions du contrat.

For the purpose of placing on the market class III devices and / or class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, another certificate issued in accordance with the provisions of the regulation (EU) 2017/745 is required.

The validity of this certificate is subject to compliance with the obligations arising from the approved quality management system and from the surveillance carried out by the notified body as required by the regulation. This certificate is bound by the conditions of the contract.

Début de validité /Effective date: May 29th, 2024 (included)

Valable jusqu'au /Expiry date: May 9th, 2028 (included)



Lionel DREUX
President

GMED - 39285 rev. 4
Modifie le certificat 39285-3

GMED • Société par Actions Simplifiée au capital de 300 000 € • RCS Paris 839 022 522 • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • lne-gmed.com

1. Le cas échéant, le nom et l'adresse du mandataire / If applicable, the name and address of the authorised representative:

MEDTRONIC B.V. - Earl Bakkenstraat 10 - 6422 PJ Heerlen – NETHERLANDS

2. Identification des sites / Identification of sites:

MEDTRONIC MINIMED - 18000 Devonshire Street - Northridge, CA 91325 - USA

3. Identification des dispositifs / Identification of devices:

Nom du dispositif médical <i>Medical device name</i>	Nom commercial <i>Commercial name</i>	Destination (DM classe IIb uniquement) <i>Intended use</i> (MD Class IIb only)	Classe du DM <i>MD Class</i>	Référence au certificat requis pour la mise sur le marché (uniquement DM classe III et IIb implantable) <i>Reference to the certificate required for placing on the market</i> (only DM class III and IIb implantable)
Guardian Link (3) Transmitter	MMT-7911	Non applicable / <i>Non applicable</i>	IIa	Non applicable / <i>Non applicable</i>
Guardian Link (3) Transmitter Kit	MMT-7910	Non applicable / <i>Non applicable</i>	IIa	Non applicable / <i>Non applicable</i>
Guardian 4 Transmitter	MMT-7841Q	The Guardian 4 transmitter is a reusable device intended to be paired with the Guardian 4 sensor as part of a continuous glucose monitoring (CGM) system for the management of diabetes. The Guardian 4 transmitter and sensor CGM system is a non-adjunctive system that may replace fingerstick blood glucose readings for treatment decisions.	IIb non implantable	Non applicable / <i>Non applicable</i>
Guardian 4 Transmitter Kit	MMT-7920Q	The Guardian 4 transmitter is indicated for single patient multiple use in people with diabetes mellitus age 7 years and older with a standalone CGM system.		

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Nom du dispositif médical <i>Medical device name</i>	Nom commercial <i>Commercial name</i>	Destination (DM classe IIb uniquement) <i>Intended use</i> (MD Class IIb only)	Classe du DM <i>MD Class</i>	Référence au certificat requis pour la mise sur le marché (uniquement DM classe III et IIb implantable) <i>Reference to the certificate required for placing on the market (only DM class III and IIb implantable)</i>
Simplera Sensor	MMT-5100JC MMT-5100JD	The Simplera™ sensor is a single-patient, single-use component of a personal CGM system. It is intended to communicate with the Simplera app via Bluetooth Low Energy (BLE) 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 Simplera™ sensor is indicated for the management of diabetes in persons ages 2 years and older.	IIb non implantable	Non applicable / <i>Non applicable</i>
Simplera System Starter Kit	MMT-5101W MMT-5101WD			
Guardian 4 Sensor	MMT-7040C MMT-7040D MMT-7040QC MMT-7040QD	The Guardian 4 sensor is a single-use, disposable device intended to be paired with the Guardian 4 transmitter as part of a continuous glucose monitoring (CGM) system for the management of diabetes. The Guardian 4 sensor and transmitter CGM system is a non-adjunctive system that may replace fingerstick blood glucose readings for treatment decisions. The Guardian Sensor 4 is indicated for single patient use in persons 7 years and older with diabetes mellitus.	IIb non implantable	Non applicable / <i>Non applicable</i>
Guardian Sensor (3)	MMT-7020C MMT-7020D	The Guardian Sensor (3) is a single-use, disposable device intended to be paired with a compatible Medtronic transmitter as part of a continuous glucose monitoring (CGM) system for the management of diabetes. The Guardian Sensor (3) is indicated for single patient use in persons of any age with diabetes mellitus.	IIb non implantable	Non applicable / <i>Non applicable</i>

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Nom du dispositif médical <i>Medical device name</i>	Nom commercial <i>Commercial name</i>	Destination (DM classe IIb uniquement) <i>Intended use</i> (MD Class IIb only)	Classe du DM <i>MD Class</i>	Référence au certificat requis pour la mise sur le marché (uniquement DM classe III et IIb implantable) <i>Reference to the certificate required for placing on the market (only DM class III and IIb implantable)</i>
Simplera Sync™ Sensor	MMT-5120C MMT-5120D	The Simplera Sync™ 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 Simplera Sync™ Sensor is indicated for the management of diabetes in persons ages 2 years and older.	IIb non implantable	Non applicable / Non applicable
Guardian 4 Transmitter Starter Kit	MMT-7840	The Guardian 4 transmitter is a reusable device intended to be paired with the Guardian 4 sensor as part of a continuous glucose monitoring (CGM) system for the management of diabetes. The Guardian 4 transmitter and sensor CGM system is a non-adjunctive system that may replace fingerstick blood glucose readings for treatment decisions. The Guardian 4 transmitter is indicated for single patient	IIb non implantable	Non applicable / Non applicable
Guardian 4 Transmitter	MMT-7841	multiple use in people with diabetes mellitus age 7 years and older when connected to a compatible Medtronic Insulin pump		

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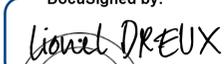
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4. Historique du certificat / Certificate history:

Référence au certificat précédent <i>Reference to the preceding certificate</i>	Date de délivrance <i>Date of issue</i>	Modifications apportées <i>Identification of the changes</i>
39285 rev. 0	10/05/2023 05/10/2023	Ajout de références / <i>Addition of references</i> MMT-5101W - MMT-5101WD MMT-7040C - MMT-7040D MMT-7040QC - MMT-7040QD MMT-7020C - MMT-7020D MMT-5120C - MMT-5120D MMT-7840 - MMT-7841
39285 rev. 1	26/07/2023 07/26/2023	Changement de nom du dispositif Instinct™ Sensor (MMT- 5120C/MMT-5120D) en Simplera Sync™ Sensor / <i>Rebranding the device name from Instinct™ Sensor (MMT- 5120C/MMT-5120D) to Simplera Sync™ Sensor.</i>
39285 rev. 2	22/12/2023 12/22/2023	Changement de nom du dispositif Simplera Sync™ Sensor en Instinct™ Sensor (MMT- 5120C/MMT-5120D) / <i>Rebranding the device name from Simplera Sync™ Sensor to Instinct™ Sensor (MMT- 5120C/MMT-5120D).</i>
39285 rev. 3	07/02/2024 02/07/2024	Changement de nom du dispositif Instinct™ Sensor (MMT- 5120C/MMT-5120D) en Simplera Sync™ Sensor / <i>Rebranding the device name from Instinct™ Sensor (MMT- 5120C/MMT-5120D) to Simplera Sync™ Sensor.</i>

5. Le cas échéant, les informations spécifiques relatives aux limitations de la validité du certificat / If applicable, specific information relating to the limitations to the validity of the certificate : Non applicable / Not applicable.

6. Le cas échéant, les informations spécifiques relatives à la surveillance effectuée dans le cadre du maintien du certificat / If applicable, specific information relating to the surveillance carried out in the context of maintaining the certificate : Non applicable / Not applicable

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