CERTIFICAT UE DE SYSTEME DE GESTION DE LA QUALITE
Règlement (UE) 2017/745, Annexe IX Chapitres I et III

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
Regulation (EU) 2017/745, Annex IX Chapters I and III

Certificat/*Certificate:* N° 39285 rev. 0

Délivré le/*Issued on:* May 10th, 2023

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 référencé(s) P602273 - P605513, 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) referenced P602273 - P605513, 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 IIb implantables et/ou de classe III, un autre certificat délivré conformément aux dispositions du règlement (UE) 2017/745 est requis.

For the purpose of placing on the market implantable class IIb and / or class III devices, another certificate issued in accordance with the provisions of the regulation (EU) 2017/745 is required.

Début de validité /*Effective date:* May 10th, 2023 (included)

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

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.

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.

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Lionel DREUX
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Lionel DREUX
President

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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 *Medical device name*	Nom commercial *Commercial name*	Destination **(DM classe IIb uniquement)** *Intended use* ***(MD Class IIb only)***	Classe du DM *MD Class*	Référence au certificat requis pour la mise sur le marché **(uniquement DM classe III et IIb implantable)** *Reference to the certificate required for placing on the market* ***(only DM class III and IIb implantable)***
Guardian Link (3) Transmitter	MMT-7911	Non applicable /*Non applicable*	IIa	Non applicable / *Non applicable*
Guardian Link (3) Transmitter Kit	MMT-7910	Non applicable /*Non applicable*	IIa	Non applicable / *Non applicable*
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. 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.	IIb non implantable	Non applicable / *Non applicable*
Guardian 4 Transmitter Kit	MMT-7920Q	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 multiple use in people with diabetes mellitus age 7 years and older with a standalone CGM system.	IIb non implantable	Non applicable / *Non applicable*

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Lionel DREUX
President

Simplera	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 / *Non applicable*

4. Historique du certificat / *Certificate history:*

Référence au certificat précédent *Reference to the preceeding certificate*	Date de délivrance *Date of issue*	Modifications apportées *Identification of the changes*
Non applicable / *Non applicable*	Non applicable / *Non applicable*	Non applicable / *Non applicable*

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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Lionel DREUX
President