EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 767470 R000

Manufacturer: Medtrum Technologies Inc.

Address:
7F, Building 8
No. 200 Niudun Road
Free Trade Zone
Shanghai
201203
China

Single Registration Number: CN-MF-000001942

EU Authorised Representative: Medtrum B.V.

Address:
Hallenweg 24
5683 CT Best
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2023-12-21**

Current Issue Date: **2024-11-11**

Starting Validity Date: **2024-11-11**

Expiry Date: **2028-12-20**

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Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
Insulin Management System	See MDR 803592

Class IIb under Rule 12 – Administer and/or remove a medicinal substance	Intended purpose
Insulin Pump system (Personal Diabetes Manager (PDM), Pump Base and Reservoir Patch)	The Insulin Pump is indicated for use in people (ages 2 to 75 years) with diabetes. The system is intended for single patient use and should be used under the guidance of a healthcare provider. The Insulin Pump is indicated for the continuous subcutaneous delivery of insulin.

Class IIb	Intended purpose
Continuous Glucose Monitoring System (Transmitter, Personal Diabetes Manager (PDM), and Glucose Sensor)	The Continuous Glucose Monitoring System is indicated for use in people (ages 2 to 75 years) with diabetes. The system is intended for single patient use. The Continuous Glucose Monitoring System is indicated for continuous monitoring of interstitial fluid glucose levels.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-12-21	3640233	Issued
2024-09-05	30095405	Supplemented - Addition of Insulin Management System and Continuous Glucose Monitoring System.
Current	30289180	Amended – EU representative address changed to: Hallenweg 24 5683 CT Best The Netherlands

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