EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 803592 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 assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III 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: **2024-09-04**

Current Issue Date: **2024-12-02**

Starting Validity Date: **2024-12-02**

Expiry Date: **2029-09-03**

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Device Schedule:

Intended Purpose as per the Instructions for Use:

The Insulin Management System (TouchCare System) is indicated for use by people age 2-75 years with type 1 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, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

The CGM System is indicated for continuous monitoring of interstitial fluid glucose levels and detection of possible low and high glucose episodes. Interpretation of the CGM System results should be based on the glucose trends and several sequential readings.

The Insulin Management System (TouchCare System) includes an APGO technology, which can automatically adjust the insulin delivery based on the glucose trends and sequential readings from the CGM. The Insulin Pump can be used with or without APGO enabled.

Risk Classification: Class III

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Basic UDI-DI**
Insulin Management System	SY-018 SY-018MM SY-018MG	MDA 0203 MDA 0306 MDN 1202	69711236805516V
	SY-201 SY-201MM SY-201MG		69711236809267J
	SY-202 SY-202MM SY-202MG		69711236814597F
	SY-301 SY-301MM SY-301MG		69711236816026U

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Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Basic UDI-DI**
Insulin Management System	SY-401 SY-401MM SY-401MG	MDA 0203 MDA 0306 MDN 1202	69711236812997H

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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
2024-09-04	30095410	Issued
Current	30290362	Amended – change of EU representative address to: Hallenweg 24 5683 CT Best The Netherlands Supplemented – Addition of new models: SY-018MM SY-018MG SY-201MM SY-201MG SY-202MM SY-202MG SY-301MM SY-301MG SY-401MM SY-401MG

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