

Self-declaration Confirming

To Whom It May Concern:

This is to confirm that the Full Quality Assurance System--- MDD 93/42/EEC Annex II certificate.

Manufacturer:

MEDTRUM TECHNOLOGIES Inc.

Manufacturer

Building 3 and Building 8, No.200 Niudun Road, 201203 Shanghai, China

Address:

HD 60135711 0001

Registration No:

2023-08-22

Expiry date:

TÜV Rheinland LGA Products GmbH

Notified Body:

0107

Notified Body No.:

Insulin management systems, Continuous Glucose Monitoring Systems

Products:

Medtrum Technologies Inc., as a manufacturer of products Continuous Glucose Monitoring Systems and Insulin Management Systems, hereby certify that it is now certified under Medical Devices Directive (MDD) 93/42/EEC.

On 20 March 2023, Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 was published and entered into force.

Medtrum Technologies Inc., as a manufacturer of products Continuous Glucose Monitoring Systems and Insulin Management Systems, hereby declared that you meet the requirements of Regulation (EU) 2023/607 Article 120(3c).

Therefore, the medical devices manufactured by Medtrum Technologies Inc., the validity of a certificate will be automatically extended or an expired certificate will automatically considered to be valid. The end date of the transition period is 31 December 2028.

Shanghai, 07-05-2023

Place, date

Zhaoyun. He.

Management Representative