EC Declaration of Conformity

Manufacturer:

MEDTRUM TECHNOLOGIES Inc

7F, Building 8, No.200 Niudun Road, Shanghai, China

whose single Authorized Representative:

Medtrum B.V.
Nijverheidsweg 17
5683 CJ Best
The Netherlands

We, the manufacturer, herewith declare that the products

Personal Diabetes Manager (Model:FM-018)

UMDNS-Code: **61584**

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIb according to Annex II of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: HD 6013 5711 0001
Issue date: 2019-02-19
Expiry date: 2023-08-22

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: MEDTRUM TECHNOLOGIES Inc
Address: 7F, Building 8, No.200 Niudun Road, Shanghai, China

Shanghai, 08-14-2020
Place, date

Shen He.
Legally binding signature, Function