

# 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  
Glucose Sensor (Model:MD3658)

*UMDNS-Code: 59016*

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

The medical device has been assigned to class IIa 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.

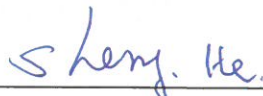
This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

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*



*Legally binding signature,*