

EC Declaration of Conformity

Manufacturer:

**MicroTech Medical (Hangzhou) Co., Ltd.
No. 108 Liuze St., Cangqian, Yuhang
District, Hangzhou, 311121 Zhejiang
P.R.China**

whose single Authorized Representative:

**Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd,
2595AA,
The Hague, Netherlands.**

We, the manufacturer, herewith declare that the products

MTM-I Ambulatory Insulin Infusion Pumps

GMDN-Code: 51038

Class: IIb

MTM-3 Insulin Infusion Pump Reservoirs

GMDN-Code: 35838

Class: IIb

HRN-N-45, HRN-N-65, HRN-S-60, HRN-S-90, MTM-4 Insulin Infusion Sets

GMDN-Code: 63262

Class: IIa

G7, G7-A, G7-B Continuous Glucose Monitoring System

GMDN-Code: NA

Class: IIa

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

The medical device has been classified according to Annex IX 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 1582538-1

Effective date: 2021-03-31

Expiry date: 2024-04-23

following the procedure relating to the EC Declaration of Conformity (Full quality assurance system) set out in Annex II, excluding (4) of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

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

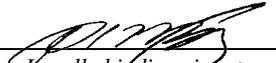


Company: MicroTech Medical (Hangzhou) Co., Ltd.

Address: No. 108 Liuze St., Cangqian, Yuhang District, Hangzhou, 311121 Zhejiang P.R.China

Hangzhou
Place

2021/12/23
date


Legally binding signature

General Manager
Function