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

Product Name	Product Code	Model Numnber	Classification	Directive
Patch Insulin Pump System kit	1001-FMTL-057	MTM-I	IIb	93/42/EEC
Patch Insulin Pump disposable reservoir	1001-FMTL-065	MTM-3	IIb	93/42/EEC
Patch Insulin Pump disposable patch cannula	1001-FMTL-124	HRN-S-60	IIa	93/42/EEC

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	2022/02/21		General Manager
Place	*date*	*Legally binding signature*	*Function*