

Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

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

**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 Number	Classification	Directive
EQ simple meter kit	010107003-2	EQ simple	List B	98/79/EC
EQ simple strips	010208007-1	EQ simple	List B	98/79/EC

meet the provisions of Directive 98/79/EC which apply to them.

Applied harmonised standards, national standards or other normative documents:

EN ISO 15197: 2015	IEC-61326-2-6: 2012
EN ISO14971: 2012	EN ISO 18113-1:2011
EN13640:2002	EN ISO 18113-4:2011
IEC 61010-1: 2010	EN ISO 18113-5: 2011
IEC 61326-1: 2012	IEC 62366:2007(First Edition)+A1:2014
IEC 61010-2-101: 2015	

The In Vitro Diagnostic Medical Device has been assigned to list B according to Annex II of the Directive 98/79/EC. It bears the mark



The product concerned has been manufactured under a quality management system according to Annex IV, excluding sections 4 and 6 of Directive 98/79/EC.

Compliance of the designated product with the Directive 98/79/EC 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.: HL 1582538-1
Effective date: 2021-03-31
Expiry date: 2024-04-23

following the procedure relating to the EC Declaration of Conformity set out in Annex IV, excluding sections 4 and 6 of Directive 98/79/EC.

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 solely under the responsibility of

Company: MicroTech Medical (Hangzhou) Co., Ltd.
Address: No. 108 Liuze St., Cangqian, Yuhang District, Hangzhou, 311121 Zhejiang
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Hangzhou 2022/2/21  General Manager
Place *date* *Legally binding signature* *Function*