

# 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

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

GMDN-Code: **NA**

Class: **Ila**

**G7, G7-A, G7-B Continuous Glucose Monitoring System consists  
of Sensor, Transmitter and PDA**

CGM System	Product Name	Product Model	Classification	Directive
G7	AIDEX CGM Sensor	G7-S01	Ila	93/42/EEC
G7	AIDEX CGM Transmitter	G7-T01	Ila	93/42/EEC
G7-A	AIDEX CGM Sensor	G7-S01A	Ila	93/42/EEC
G7-A	AIDEX CGM Transmitter	G7-T01A	Ila	93/42/EEC
G7-B	AIDEX CGM Sensor	G7-S01B	Ila	93/42/EEC
G7-B	AIDEX CGM Transmitter	G7-T01B	Ila	93/42/EEC
G7 / G7-A / G7-B	PDA	G7-P02	Ila	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, Yunqiang District, Hangzhou, 311121 Zhejiang P.R.China

Hangzhou  
*Place*

2022/02/15  
*date*



*Legally binding signature*

General Manager  
*Function*