

## Certificate

## Quality Management System EN ISO 13485:2016

Registration No.:

SX 1582538-1

Organization:

Microtech Medical (Hangzhou) Co., Ltd.

No.108 Liuze St., Cangqian, Yuhang District, Hangzhou,

311121 Zhejiang P.R. China

Scope:

Design and Development, Manufacture and Distribution of Continuous

Glucose Monitoring Systems and associated software, Insulin Management

Systems and associated software;

Design and Development, Manufacture and Distribution of in vitro diagnostic medical devices (reagents, controls, instruments) used in the monitoring of blood glucose and in the detection of the disease status including (home use, near patient/point of care) in vitro diagnostic devices

IUVRheinland

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:

244468899-200

Effective date:

2023-04-24

Expiry date:

2026-04-23

Issue date:

2023-03-15

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

