

EU Certificate

Quality Management System REGULATION (EU) 2017/745 on Medical Devices Annex IX Chapters I and III

Registration No.: HZ 1582538-1

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

EUDAMED Single
Registration No.: CN-MF-000001157

Products:

Products of class IIb:
Z120401 - GENERAL MEDICINE INSTRUMENTS
GENERAL MEDICINE DIAGNOSIS AND MONITORING
INSTRUMENTS
- Continuous Glucose Monitoring System Sensor
- Continuous Glucose Monitoring App
- Continuous Glucose Monitoring System Transmitter
- Continuous Glucose Monitoring System PDA

Authorized representative(s): CMC Medical Devices & Drugs S.L
C/Horacio Lengo N° 18 CP 29006, Málaga-Spain
ES-AR-000000293

The Notified Body hereby declares that the requirements of Annex IX, Chapter I of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.

If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 326141289-100

Effective date: 2026-01-23

Expiry date: 2029-09-03

Issue date: 2026-01-23



Herbert Zhong
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on <https://www.certipedia.com>

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-09-04
1	Products extension	2024-10-09
2	Authorized Representative change	2026-01-23

