EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HZ 2091024-1

Manufacturer: **Promisemed Hangzhou Meditech Co., Ltd.**
No. 1388 Cangxing Street,
Cangqian Community, Yuhang District,
Hangzhou City
311121 Zhejiang
P.R. China

EUDAMED Single Registration No.: CN-MF-000008465

Products: Products of Class IIa:
A010101 – Insulin Pen Needles,
A010101 – Safety Insulin Pen Needles,
V0104 – Blood Lancets,
V0104 – Heel Blood Lancets,
A020106 – Insulin Syringes,
A020106 – Safety Insulin Syringes,
A010201 – Co-axial Biopsy Devices

Authorised representative(s): OBELIS S.A
Bd. Général Wahis, 531030 Brussels, Belgium.

Certificate history		
Revision:	Description:	Issue date:
1	Initial Version	2021-07-22

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 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.: 15063511 019

Effective date: 2021-07-22

Expiry date: 2025-11-13

Issue date: 2021-07-22

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-MDR-091

TÜV Rheinland LGA Products GmbH Zertifizierung

Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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