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 – HYPODERMIC NEEDLES
- Insulin Pen Needles
A010101 – HYPODERMIC NEEDLES
- Safety Insulin Pen Needles
V010402 – LANCETS WITHOUT SAFETY SYSTEMS, SINGLE-USE
- Blood Lancets
V010401 – LANCETS WITH SAFETY SYSTEMS, SINGLE-USE
- Heel Blood Lancets
A020106 – INSULIN SYRINGES, SINGLE-USE
- Insulin Syringes
A020106 – INSULIN SYRINGES, SINGLE-USE
- Safety Insulin Syringes
A010201 – NEEDLES AND KITS - HISTOLOGICAL AND CYTOLOGICAL BIOPSY OF SOFT TISSUES
- Co-axial Biopsy Devices
A010201 – NEEDLES AND KITS - HISTOLOGICAL AND CYTOLOGICAL BIOPSY OF SOFT TISSUES
- Fine Biopsy Needles
A010105 – NEEDLES FOR COLLECTION UNDER VACUUM
- Safety Winged Blood Collection Sets
A010103 – NEEDLES AND KITS FOR IMPLANTABLE SYSTEMS (PORT)

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.: 244426617-200

Effective date: 2022-09-02

Expiry date: 2025-11-13

Issue date: 2022-09-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TUVRheinland®

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

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

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

EU Certificate

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

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
- Safety Huber Needles
A020102 – INFUSION AND IRRIGATION SYRINGES, SINGLE-USE
- Safety Sterile Syringes
A020102 – INFUSION AND IRRIGATION SYRINGES, SINGLE-USE
- Sterile Syringes with Safety Needle Combo
A020102 – INFUSION AND IRRIGATION SYRINGES, SINGLE-USE
- Sterile Syringes with Fixed Needles
A020102 – INFUSION AND IRRIGATION SYRINGES, SINGLE-USE
- Safety Syringes with Fixed Needles
A010101 – HYPODERMIC NEEDLES
- Safety Sterile Needles
A010201 – NEEDLES AND KITS - HISTOLOGICAL AND CYTOLOGICAL BIOPSY OF SOFT TISSUES
- Semi-automatic Biopsy Needles
A010201 – NEEDLES AND KITS - HISTOLOGICAL AND CYTOLOGICAL BIOPSY OF SOFT TISSUES
- Automatic Biopsy Needles
V010401 – LANCETS WITH SAFETY SYSTEMS, SINGLE-USE
- Safety Blood Lancets

Products of Class I, Sterile:
A020102 – INFUSION AND IRRIGATION SYRINGES, SINGLE-USE
- Sterile Syringes without Needles
The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions

Authorised representative(s): OBELIS S.A
Bd. Général Wahis, 53 1030 Brussels, Belgium.

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Certificate history		
Revision:	Description:	Issue date:
1	Initial Version	2021-07-22
2	Change in the scope of certification	2022-06-28
3	Change in the scope of certification	2022-09-02

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