

# 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: **Promisedmed 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.

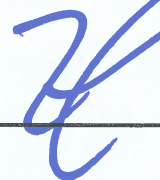

Report No.: 244426617-200

Effective date: 2022-09-02

Expiry date: 2025-11-13

Issue date: 2022-09-02



  
  
Herbert Zhong  
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.

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Registration No.: HZ 2091024-1



Manufacturer:

**Promised Hangzhou Meditech Co., Ltd.**

No. 1388 Cangxing Street,  
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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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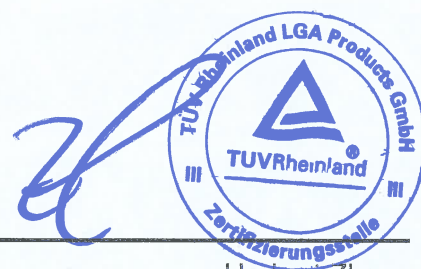
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Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
BS-MDR-091



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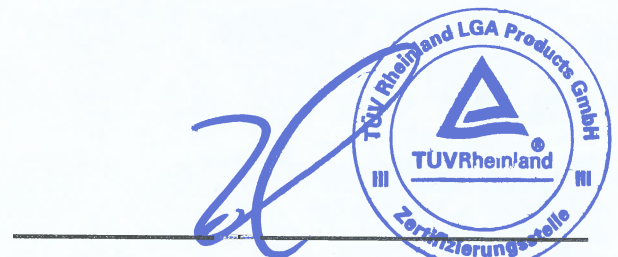
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Certificate history		
Revision:	Description:	Issue date:
1	Initial Version	2021-07-22
2	Change in the scope of certification	2022-06-28
3	Change in the scope of certification	2022-09-02



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