

# EU Certificate

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

EUDAMED Single  
Registration No.: CN-MF-000008465

### Products:

Products of class I, sterile:  
A020102 - INFUSION AND IRRIGATION SYRINGES,  
SINGLE-USE  
- Sterile Syringes without Needles  
A070103 - INFUSION LINES ADAPTERS AND  
CONNECTORS  
- Needleless Adapters  
A019001 - BLUNT NEEDLES  
- Blunt Needles  
A010180 - NEEDLES FOR INFUSION AND COLLECTION -  
ACCESSORIES  
- Blood Collection Tube Holders

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.: 326130719-200  
Effective date: 2026-04-02  
Expiry date: 2030-11-13  
Issue date: 2026-04-02



Herbert Zhong  
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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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Zentralstelle der Länder  
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www.zflg.de  
BS-MDR-091

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### Products:

G030801 - GASTROINTESTINAL ENDOSCOPY, FORCEPS,  
SINGLE-USE

- Single Use Grasping Forceps

G030803 - GASTROINTESTINAL ENDOSCOPY AND  
ECHOENDOSCOPY, BRUSHES

- Single Use Cytology Brushes

G030501 - DIGESTIVE ENDOSCOPY, RETRIEVAL DEVICES

- Retrieval Nets

U0601 - UROLOGICAL GUIDEWIRES, HYDROPHILIC &

R070299 - BRONCHOSCOPIC SURGERY INSTRUMENTS,  
SINGLE-USE - OTHER &

G030899 - INSTRUMENTS FOR GASTRO-INTESTINAL  
ENDOSCOPY AND ECO-ENDOSCOPY, SINGLE-USE -  
OTHER

- Endoscopic Guidewires

The scope of certification is limited to the aspects relating to  
establishing, securing and maintaining sterile conditions

### Products of class IIa:

A010101 - HYPODERMIC NEEDLES

- Insulin Pen Needles

- Safety Insulin Pen Needles

- Safety Sterile Needles

- Sterile Needles

A010103 - NEEDLES AND KITS FOR IMPLANTABLE  
SYSTEMS (PORT)

- Safety Huber Needles

- Regular Huber Needles



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### Products:

- A010105 - NEEDLES FOR COLLECTION UNDER VACUUM
  - Safety Winged Blood Collection Sets
  - Winged Blood Collection Sets
- A010201 - NEEDLES AND KITS - HISTOLOGICAL AND CYTOLOGICAL BIOPSY OF SOFT TISSUES
  - Co-axial Biopsy Devices
  - Fine Biopsy Needles
  - Semi-automatic Biopsy Needles
  - Automatic Biopsy Needles
  - Endoscopic Ultrasound Needles
  - Full Core Biopsy Needles
- A020102 - INFUSION AND IRRIGATION SYRINGES, SINGLE-USE
  - Safety Sterile Syringes
  - Sterile Syringes with Fixed Needles
- A020106 - INSULIN SYRINGES, SINGLE-USE
  - Insulin Syringes
  - Safety Insulin Syringes
  - Safety Sterile Syringes
- A019012 - BREAST NODULES AND OTHER STRUCTURES LOCALISATION NEEDLES AND SYSTEMS
  - Breast Localization Wires
- A060201 - EXTERNAL DRAINAGE CATHETERS AND KITS (ABSCESSSES, GALLSTONES, CYSTS)
  - Multipurpose Drainage Catheters



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### Products:

V010401 - LANCETS WITH SAFETY SYSTEMS, SINGLE-  
USE

- Heel Blood Lancets
- Safety Blood Lancets

V010402 - LANCETS WITHOUT SAFETY SYSTEMS,  
SINGLE-USE

- Blood Lancets

G030201 - DIGESTIVE ENDOSCOPY, NEEDLES

- Endoscopic Injection Needles

G030801 - GASTROINTESTINAL ENDOSCOPY, FORCEPS,  
SINGLE-USE &

R070201 - BRONCHOSCOPIC SURGERY FORCEPS,  
SINGLE-USE &

U090301 - FORCEPS FOR UROGENITAL ENDOSCOPY,  
SINGLE-USE

- Single Use Biopsy Forceps

G030301 - POLYPECTOMY SNARES

- Cold Polypectomy Snares

U090101 - URINARY STONE RETRIEVAL BASKETS &

G030501 - DIGESTIVE ENDOSCOPY, RETRIEVAL DEVICES

- Stone Retrieval Baskets

U030102 - URETHRAL AND URETERAL DILATORS

- Ureteral Access Sheaths

Z120208 - PULMONARY ENDOSCOPIC INSTRUMENTS

- Single-use Flexible Bronchoscopes

Z120205 - UPPER GASTROINTESTINAL TRACT  
ENDOSCOPY INSTRUMENTS

- Single-use Flexible Choledochoscopes



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Products:

Z120207 - GENITOURINARY ENDOSCOPY INSTRUMENTS  
- Single-use Flexible Ureterscopes  
- Single-use Flexible Cystoscopes

Products of class IIb:

G030202 - DIGESTIVE ENDOSCOPY, HAEMOSTASIS  
DEVICES

DIGESTIVE ENDOSCOPY, HAEMOSTASIS CLIPS

- Single Use Hemoclips

G030301 - POLYPECTOMY DEVICES

POLYPECTOMY SNARES

- Polypectomy Snares

G030801 - GASTROINTESTINAL ENDOSCOPY AND  
ECHOENDOSCOPY, SINGLE-USE INSTRUMENTS

GASTROINTESTINAL ENDOSCOPY, FORCEPS, SINGLE-  
USE

- Hot Biopsy Forceps

Authorized representative(s): OBELIS S.A  
Bd. Général Wahis, 53, 1030 Brussels, Belgium.  
BE-AR-000000106



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Certificate history		
Revision:	Description:	Issue date:
8	Re-certification. Replaces certificate HZ 2091024-1 Rev. 7 issued 2024-10-23	2025-08-21
9	Scope extension, products of class Is: U0601, R070299, G030899 and class Ila: U030102, Z120205, Z120207, Z120208	2025-10-29
10	Scope extension, products of class Ila: G030301	2025-12-02
11	Scope extension, products of class Ila: G030801	2026-02-09
12	Scope extension, products of class Ila: A010201, A020106, G030801 & R070201 & U090301; scope reduction, products of class Is: A070103, G030704, A030201, products of class Ila: A010202, A020102	2026-04-02

