

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

EUDAMED Single Registration No.: CN-MF-000008465

Products: 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
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

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.: 244533112-200

Effective date: 2024-03-14

Expiry date: 2025-11-13

Issue date: 2024-03-14



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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für Gesundheitsschutz
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- Co-axial Biopsy Devices
- Fine Biopsy Needles
- Semi-automatic Biopsy Needles
- Automatic Biopsy Needles
- A010202 – BONE MARROW BIOPSY NEEDLES AND KITS
- Bone Marrow Biopsy Needles
- A020102 – INFUSION AND IRRIGATION SYRINGES,
SINGLE-USE
- Safety Sterile Syringes
- Sterile Syringes with Safety Needle Combo
- Sterile Syringes with Fixed Needles
- Safety Syringes with Fixed Needles
- Auto-Disable Syringes
- A020106 – INSULIN SYRINGES, SINGLE-USE
- Insulin Syringes
- Safety Insulin Syringes
- A019012 – BREAST NODULES AND OTHER STRUCTURES
LOCALISATION NEEDLES AND SYSTEMS
- Breast Localization Wires
- A060201 - EXTERNAL DRAINAGE CATHETERS AND KITS
(ABSCESSSES, GALLSTONES, CYSTS)

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- Multipurpose Drainage Catheters
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
- Single Use Biopsy Forceps
G030301 - POLYPECTOMY SNARES
- Cold Polypectomy Snares

Products of Class I, Sterile:
A020102 – INFUSION AND IRRIGATION SYRINGES,
SINGLE-USE

- Sterile Syringes without Needles
A070103 – INFUSION LINES ADAPTERS AND

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CONNECTORS

- Needleless Adapters

- Heparin Plugs

A019001 – BLUNT NEEDLES

- Blunt Needles

A010180 – NEEDLES FOR INFUSION AND COLLECTION -
ACCESSORIES

- Blood Collection Tube Holders

G030704 – COLON DYE SPRAYING CATHETERS

- Spraying Catheters for Single Use

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

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

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

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
4	Change in the scope of certification	2023-08-08
5	Products Extension	2024-03-14

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