

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 2011845-1

Manufacturer: Jiangsu Guangyi Medical Dressing Co., Ltd.
No.6 Jianzhong Road,
Xinpu Economic Development Zone, Haizhou
District, Lianyungang,
222344 Jiangsu
P.R. China

EUDAMED Single
Registration No.: CN-MF-000009827

Products: Products of Class I, Sterile:
M010103 - COTTON PAD
M020102 - COTTON GAUZES, FOLDED
M020201 - NON-WOVEN FOLDED GAUZES
M040101 - ADHESIVE DRESSINGS, WITH ABSORBENT
PAD
M040102 - FIXING DRESSINGS
M040199 - PREPARED DRESSINGS - OTHER
M040406 - POLYURETHANE DRESSINGS
T0306 - PATIENT PROTECTION DEVICES DURING
CLINICAL PROCEDURES

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

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.: 190148828-120

Effective date: 2024-04-25

Expiry date: 2029-04-24

Issue date: 2024-04-25



Jing Zhang
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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Zentralstelle der Länder
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REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III**

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222344 Jiangsu
P.R. China
EUDAMED Single Registration No.: CN-MF-000009827
Authorized representative(s): SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7, 2909 VA Capelle aan den IJssel, The Netherlands

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-04-25

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