

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60107079 0001

Report No.: 15091168 001

Manufacturer: Jiangsu Medplus Non-woven
Manufacturer Co., Ltd.
Industrial Park, Jiangdu Bridge
225211 Yangzhou, Jiangsu
China

Products: Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: DD 60098994 0001

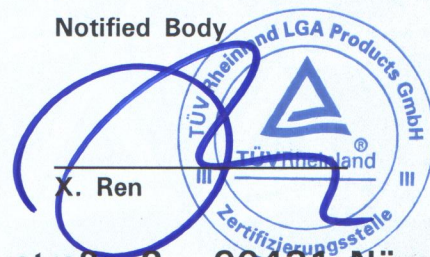
Expiry Date: 2020-12-22

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2015-12-23

Date: 2015-12-23

Notified Body



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60107079 0001
Report No.: 15091168 001

Manufacturer: Jiangsu Medplus Non-woven
Manufacturer Co., Ltd.
Industrial Park, Jiangdu Bridge
225211 Yangzhou, Jiangsu
China

Products:

Surgical Gloves, Sterile X-ray Detectable Gauze Swabs,
Sterile X-ray Detectable Gauze Balls

Aspects of manufacture concerned with securing and
maintaining sterile conditions:

Disposable Surgical Gowns, Disposable Face Masks,
Disposable Shoe Covers, Disposable Caps, Surgical
Drapes, Surgical Packs, Examination Gloves, Bandages,
Gauze Swabs, Gauze Balls, Underpads

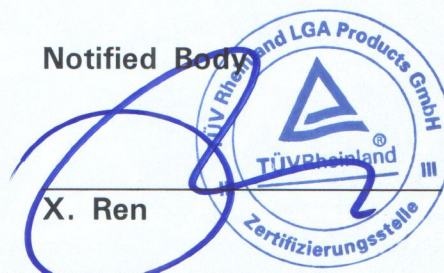
Site included:

No.217 East Wencheng Road, Economic Development Zone,
Siyang, Jiangsu, 223700, China

Date: 2015-12-23

Notified Body

X. Ren



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Jiangsu Medplus Non-woven
Manufacturer Co., Ltd.
Industrial Park, Jiangdu Bridge
225211 Yangzhou, Jiangsu
China**

has established and applies a quality management system for medical devices
for the following scope:

Manufacture and Distribution of Medical Devices

(see attachment for products and additional site included)

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012
EN ISO 13485:2012/AC:2012**

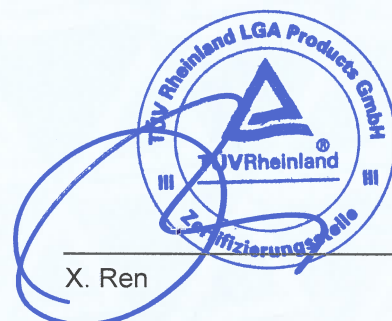
are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2017-05-27
Certificate Registration No.: SX 60119598 0001
An audit was performed. Report No.: 15091168 003
This Certificate is valid until: 2018-12-22

Certification Body



Date 2017-05-27



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev.0

**Attachment to
Certificate**

Registration No.: SX 60119598 0001
Report No.: 15091168 003

Organization:

**Jiangsu Medplus Non-woven
Manufacturer Co., Ltd.**
Industrial Park, Jiangdu Bridge
225211 Yangzhou, Jiangsu
China

Scope:

Products:

Disposable Surgical Gowns, Disposable Face Masks,
Disposable Shoe Covers, Disposable Caps, Surgical
Drapes, Surgical Packs, Surgical Gloves, Sterile X-ray
Detectable Gauze Swabs, Sterile X-ray Detectable Gauze
Balls, Examination Gloves, Bandages, Gauze Swabs,
Gauze Balls, Underpads, Non-sterile Gowns

Site included:

No.217 East Wencheng Road, Economic Development Zone,
Siyang, Jiangsu, 223700, China

Manufacture and Distribution of the a.m. products

Certification Body



Date: 2017-05-27

