EC Certificate

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

Registration No.: DD 60127882 0001

Report No.: 15056888 007

Manufacturer:
Xiantao Fushi Protective
Products Co., Ltd.
Zhongling Industrial Zone
Pengchang Town, Xiantao City
433018 Hubei
China

Products:
Aspects of manufacture concerned with securing and maintaining sterile conditions of Surgical Gowns, Caps, Masks, Coveralls, Shoe Covers, Isolation Gowns, Surgical Drapes
(see attachment for additional site included)

Replaces Approval, Registration No.: DD 60082487 0001

Expiry Date: 2023-02-07

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.

Notified Body

Effective Date: 2018-03-20

Date: 2018-03-20

X. Ren

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.

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60127882 0001
Report No.: 15056888 007

Manufacturer:
Xiantao Fushi Protective
Products Co., Ltd.
Zhongling Industrial Zone
Pengchang Town, Xiantao City
433018 Hubei
China

Site included:

FULLSTAR Non-Woven Products Co., Ltd.
Gongtong Industrial Zone, Xiantao City,
Hubei Province, China

Notified Body

Date: 2018-03-20

X. Ren