



EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 003747 0002 Rev. 00

Manufacturer Xianning Full Guard

Medical Products Co., Ltd.

Yongan East Road

Wenquan Economic Development Zone 437100 Xianning City, Hubei Province PEOPLE'S REPUBLIC OF CHINA

EC-Representative: ZOUSTECH S.L.

Pso. Castellana, 141 - Planta 19, 28046 Madrid, SPAIN

Product
Disposable Surgical Gown,
Category(ies):
Disposable Medical Hole Tow

Disposable Medical Hole Towel,
Disposable Medium Drapes

Disposable Sterilized Dressing Packs

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:

SH18131701

Valid from:

2018-11-05

Valid until:

2023-11-04

Date,

2018-11-05

Stefan Preiß

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EC Certificate

Production Quality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex V (Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 003747 0002 Rev. 00

Facility(ies):

Xianning Full Guard Medical Products Co., Ltd. Yongan East Road, Wenquan Economic Development Zone, 437100 Xianning City, Hubei Province, PEOPLE'S REPUBLIC OF CHINA







Certificate

No. Q6 003747 0001 Rev. 01

Applied Standard(s): EN ISO 13485:2016

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016)

DIN EN ISO 13485:2016

Xianning Full Guard Medical Products Co., Ltd. Facility(ies):

Yongan East Road, Wenguan Economic Development Zone, 437100 Xianning City, Hubei Province, PEOPLE'S REPUBLIC OF CHINA

See scope of certificate







Certificate

No. Q6 003747 0001 Rev. 01

Holder of Certificate: Xianning Full Guard

Medical Products Co., Ltd.

Yongan East Road

Wenquan Economic Development Zone 437100 Xianning City, Hubei Province PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Production and Distribution of

Disposable Surgical Gown, Disposable Medical Hole Towel,

Disposable Medical Hole Towel, Disposable Medium Drapes,

Disposable Sterilized Dressing Packs

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q6 003747 0001 Rev. 01

Report No.: SH21131701

 Valid from:
 2021-11-11

 Valid until:
 2024-11-04

Date, 2021-11-11 Christoph Dicks

Head of Certification/Notified Body