



Product Service

Certificate

No. Q6 096662 0003 Rev. 01

Holder of Certificate: **3A Medical Products Co., Ltd.**
Yu An Industrial Park
230001 Liu An
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): 3A Medical Products Co., Ltd.
Yu An Industrial Park, 230001 Liu An, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Production and Distribution of Surgical Gown, Surgical Drape, Surgical Pack, Coverall, and Isolation Gown**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
DIN EN ISO 13485:2016

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). See also notes overleaf.

Report No.: SH19111104

Valid from: 2019-10-17

Valid until: 2022-10-16

Date, 2019-08-30

Stefan Preiß
Head of Certification/Notified Body



Product Service

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_16 08 96662 002

Manufacturer: 3A Medical Products Co., Ltd.

Yu An Industrial Park
 230001 Liu An
 PEOPLE'S REPUBLIC OF CHINA



EC-Representative: Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße 80
 20537 Hamburg
 GERMANY

Product Category(ies): Surgical Gown, Surgical Drape, Surgical Pack

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.: SH16111101

Valid from: 2016-10-17

Valid until: 2021-10-16



Date, 2016-10-17

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Production Quality Assurance System

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