



Certificate

No. Q5 094395 0003 Rev. 01

Holder of Certificate: Union Medical Shenzhen Co.,Ltd.

Room 603, Building 3

Fantasia MIC Plaza, Nanhai Avenue

Nanshan District 518062 Shenzhen

PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Union Medical Shenzhen Co.,Ltd.

Room 603, Building 3, Fantasia MIC Plaza, Nanhai Avenue, Nanshan District, 518062 Shenzhen, PEOPLE'S REPUBLIC OF

CHINA

Union Medical Shenzhen Co.,Ltd.

Floor 1-2, Building 8, HKC Industrial Park, Industry 2nd Road, Shiyan, Bao'an District, 518108 Shenzhen, PEOPLE'S REPUBLIC

OF CHINA

Certification Mark:



Scope of Certificate: Design and Development, Production and

Distribution of Disposable High Pressure Syringe

and Disposable Pressure Connector Tube

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, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: GZ1924501

 Valid from:
 2019-07-02

 Valid until:
 2022-06-21

Date, 2019-07-02 Stefan Pre

Head of Certification/Notified Body

1. Punil

FIKAT



EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 15 12 94395 002

Manufacturer: Union Medical Shenzhen Co.,Ltd.

Room 603. Building 3

Fantasia MIC Plaza, Nanhai Avenue

Nanshan District 518062 Shenzhen

PEOPLE'S REPUBLIC OF CHINA



Shanghai International Holding EC-Representative:

Corp. GmbH (Europe)

Eiffestraße 80 20537 Hamburg **GERMANY**

Disposable High Pressure Syringe and **Product Disposable Pressure Connector Tube** Category(ies):

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 7484026717

Valid from: 2016-06-22 Valid until: 2021-06-21

Date, 2016-06-22



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

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EC Certificate Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 15 12 94395 002

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