



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 094395 0004 Rev. 00

Manufacturer:

Union Medical Shenzhen Co.,Ltd.

Room 603, Building 3

Fantasia MIC Plaza, Nanhai Avenue

Nanshan District

518062 Shenzhen

PEOPLE'S REPUBLIC OF CHINA

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

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. 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:G10943950004Rev.00

Report No.: GZ2024503

Valid from: 2021-02-02

Valid until: 2024-05-26

Date, 2021-02-02

Christoph Dicks

Head of Certification/Notified Body