



Product Service

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

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

Eiffestraße 80
20537 Hamburg
GERMANY

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. See also notes overleaf.

Report No.:

7484026717

Valid from:

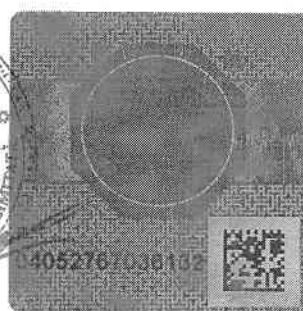
2016-06-22

Valid until:

2021-06-22

Date, 2016-06-22

Stefan Preitl



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

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(Devices in Class IIa, IIb or III)

No. G1 15 12 94395 002**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





Product Service

CERTIFICATE

No. Q1N 15 12 94395 001

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

**Certification Mark:****Scope of Certificate:** Design and Development, Production and Distribution of Disposable High Pressure Syringe and Disposable Pressure Connector Tube

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.: 7484026717**Valid from:** 2016-06-22**Valid until:** 2019-06-21**Date,** 2016-06-22

Stefan Preiß



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Deutsche
Akkreditierungsstelle
D-2M-11321-01-00



Product Service

CERTIFICATE**No. Q1N 15 12 94395 001****Applied Standard(s):**

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

Facility(ies):

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