





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:** 2021-06-21

**Date,** 2016-06-22

Stefan Preiß



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

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#### Facility(ies):

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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