ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Digitally signed by Iurcu Nicolae
Date: 2019.11.20 10:28:17 EET
Reason: MoldSign Signature
Location: Moldova

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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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