unionmed

Manufacturer's Authorization

Date: September 30th, 2016

To whom this may concern,

We, "**Union Medical Shenzhen Co.,Ltd.**", having facilities at "Room 603, Building 3, Fantasia MIC Plaza, Nanhai Avenue, Nanshan District, 518062 Shenzhen, P.R.China" and "Floor 1-2,Building 8,HKC Industrial Park, Industry 2nd Road, Shiyan, Bao'an District, 518108 Shenzhen, P.R.China"

do hereby confirm that "**S.C. "GT-TEHNOLOGII" S.R.L.**" located at "str-la Criuleni 63A, Chisinau, MD-2059, Republic of Moldova" is our authorized distributor of the Disposable High Pressure Syringe and Disposable Pressure Connector Tube, manufactured by us. "**S.C. "GT-TEHNOLOGII" S.R.L.**" is authorized to submit tenders on our behalf in Moldova, concerning the products of Disposable High Pressure Syringe, Disposable Pressure Connector Tube.

Signature: *For and on behalf of*
Union Medical Shenzhen Co., Ltd.
优尼麦迪克器械(深圳)有限公司
.....
Authorized Signature(s)

Position: Sales Department Manager

Duly authorized to sign this Authorization on behalf of Union Medical Shenzhen Co.,Ltd.

Dated on: September 30th 2016

UNION MEDICAL SHENZHEN CO., LTD.
Add/ Room 603, Building 3, Fantasia MIC Plaza, Nanhai Avenue, Nanshan District, Shenzhen, China P.C./ 518062
Tel/ +86 755 2669 6966 Fax/ +86 755 2681 8966 Web/ www.umed.com

Digitally signed by Iurcu Nicolae
Date: 2019.04.03 11:44:33 EEST
Reason: MoldSign Signature
Location: Moldova

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

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

TÜV®

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

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

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

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

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:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

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

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Date, 2016-06-22

Stefan Preiß

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV®

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

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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