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

Digitally signed by Jighili Tatiana
Date: 2022.11.21 12:34:14 EET
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Location: Moldova

Product Service

C E R T I F I C A T E

No. Q1N 12 06 49578 012

Holder of Certificate: **Shenzhen East Medical Technology Co., Ltd.**

No.190,longping Road,Huate Industrial Zone,Longgang District,
Shenzhen,Guangdong China 518116
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

No.190,longping Road,Huate Industrial Zone,Longgang District,
Shenzhen,Guangdong China 518116
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate:

Design and Development, Production, Sales and Servicing of Ultrasound Diagnostic Device, Full Digital Ultrasound Diagnostic Device, Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer, Hematology Analyzer,Electrolyte Analyzer, Glycated Hemoglobin HbA1c Analyzer, Coagulation Analyzer

Applied Standard(s):

EN ISO 13485: 2012
ISO 13485: 2003
Medical Devices – Quality Management Systems – Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: BJ1289804
Valid from: 2019-10-17
Valid until: 2023-09-30

Date, 2019-07-22

Hans-Heiner Junker

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TÜV SÜD Product Service GmbH
Zertifizierstelle
Ridlerstr. 65 · 80339 München
Germany

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-999.98.12-46

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 12 09 49578 014

Manufacturer:

Shenzhen East Medical Technology Co., Ltd.
No.190,longping Road,Huate Industrial Zone,Longgang District,
Shenzhen,Guangdong China 518116
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Trading Corp. GmbH (Hamburg)
Eiffestrasse 80
20537 Hamburg
GERMANY

Product Category(ies):

Full Digital Ultrasound Diagnostic Device, Biochemical Analyzer, Hematology Analyzer, Electrolyte Analyzer, Microplate Reader, Glycated Hemoglobin HbA1c Analyzer, Coagulation Analyzer

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.: BJ1289807

Valid from: 2019-10-17
Valid until: 2023-10-20

333956

Date, 2019-07-22

Hans-Heiner Junker

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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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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 12 09 49578 014

Facility(ies): No.190,longping Road,Huate Industrial Zone,Longgang District, Shenzhen,Guangdong China 518116

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