ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ 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 17 12 78995 012

Manufacturer:

BORSAM Biomedical Instruments Co., Ltd.
Rm. 502, University Innovation PARK
Lishan road
Xili Town
518055 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Prolinx GmbH
Brehmstr. 56
40239 Duesseldorf
GERMANY

Product Category(ies):

Holter ECG Workstation, ECG Event Recorder and Ambulatory Blood Pressure Measurement System

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.: GZ1705701

Valid from: 2018-03-14
Valid until: 2022-02-07

Date, 2018-03-14

Stefan Preiß

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

Digitally signed by Jighili Tatiana
Date: 2020.07.31 11:24:32 EEST
Reason: MoldSign Signature
Location: Moldova

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ 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 17 12 78995 012

Facility(ies):

BORSAM Biomedical Instruments Co., Ltd.
Rm. 502, University Innovation PARK, Lishan road, Xili Town,
518055 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 089075 0007 Rev. 00

Manufacturer:

Dawei Medical (Jiangsu) Co., Ltd.
28 Jinqiao Road
Economic and Technological Development Zone
221004 Xuzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Dawei Medical (Jiangsu) Co., Ltd.
28 Jinqiao Road, Economic and Technological Development Zone, 221004 Xuzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Ultrasonic Diagnostic System, Color Ultrasonic Diagnostic Apparatus**

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.: SH19878EXT01

Valid from: 2019-07-25
Valid until: 2024-05-26

Date, 2019-07-25

Stefan Preiß
Head of Certification/Notified Body

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

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ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ 認證證書

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Product Service

Certificate

No. Q5 089075 0005 Rev. 00

Holder of Certificate: **Dawei Medical (Jiangsu) Co., Ltd.**
28 Jinqiao Road
Economic and Technological Development Zone
221004 Xuzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Dawei Medical (Jiangsu) Co., Ltd.
28 Jinqiao Road, Economic and Technological Development Zone, 221004 Xuzhou, Jiangsu, 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 Ultrasonic Diagnostic Systems and Color Ultrasonic Diagnostic Apparatus**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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.: SH1887805

Valid from: 2019-06-21
Valid until: 2021-02-03

Date, 2019-06-21

Stefan Preiß
Head of Certification/Notified Body

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