



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:**

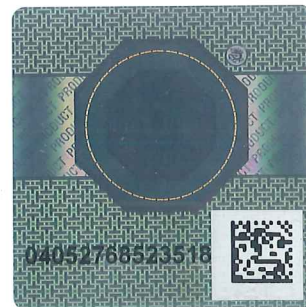
2018-03-14

**Valid until:**

2022-02-07

**Date,** 2018-03-14

Stefan Preiß



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

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Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
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**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



# 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:**



### 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

S. Pennit

Stefan Preiß  
Head of Certification/Notified Body