

Benannt durch/Designated by Zentraistelle der Lander fur Gesundheitsschutz bei Arzneimitteln und Medizinprodukten ZLG-BS-244.10,08





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 TŪV SŪD 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: Valid until: 2019-07-25 2024-05-26

Date,

2019-07-25

1. Pumil

Stefan Preiß Head of Certification/Notified Body

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