



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

Dawei Medical (Jiangsu) Co., Ltd. Manufacturer:

28 Jingiao Road

Economic and Technological Development Zone

221004 Xuzhou, Jiangsu

PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Dawei Medical (Jiangsu) Co., Ltd.

28 Jingiao 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.

SH19878EXT01 Report No.:

2019-07-25 Valid from:

2024-05-26 Valid until:

2019-07-25 1. Punil Date,

Stefan Preiß

Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany