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

Digitally signed by Jighili Tatiana
Date: 2020.06.05 09:58:01 EEST
Reason: MoldSign Signature
Location: Moldova

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

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

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A4 / 07.17

ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ 認證證書

Declaration of Conformity

Manufacturer: Dawei Medical (Jiangsu) Co.,Ltd.
28 Jinqiao Road, Economic and Technological Development Zone, Xuzhou, 221004 Jiangsu, China

EC Representative:
Name: Luxus Lebenswelt GmbH
Add: Kochstr. 1, 47877, Willich, Germany
DIMDI Code: DE/0000047791
Tax Number: DE305829099
Contact Person: Lin Sun
Tel/Fax: 0049-1715605732
E-mail: Info.m@luxuslw.de

Product Name: Color Ultrasonic Diagnostic Apparatus

UMDN Code: 15067

Classification (MDD, Annex IX): Class IIa, Rule 10

Conformity Assessment Route: Annex II exl.section 4

We herewith declare in our own responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.A statement that the manufacturer is exclusively responsible for the DoC.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices MDD 93/42/EEC(as amended by 2007/47/EC).

Standard Applied:

EN ISO 15223-1:2016,EN 1041:2013,EN ISO 13485:2016,EN ISO 14971:2012,EN 60601-1:2006+A1:2013, EN 60601-1-2:2015,EN 60601-2-37:2008+A11:2011+A1:2015 EN 62366:2015, EN 62304:2015, IEC 60227-1:2007 ,ISO10993-1:2009, ISO10993-5:2009,ISO10993-10:2013

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany

Identification number: CE0123

(EC) Certificate(s): G1 0890750007Rev.00

Expire date of the Certificate: 2024-05-26

Start of CE Marking: 2015-02-04

Place, Date of Issue: Xuzhou, 2019-07-25

Signature:

Name: Xiuqi Jian

Position: Xuzhou, Jiansu, China Quality Management

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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