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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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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 093557 0009 Rev. 00

Manufacturer:

Shenzhen Wisonic Medical Technology Co., Ltd.

1st, 2nd & 5th Floor, No.6 Building
Pingshan Technology Park
Taoyuan Street, Nanshan District
518055 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Shenzhen Wisonic Medical Technology Co., Ltd.
1st, 2nd & 5th Floor, No.6 Building, Pingshan Technology Park,
Taoyuan Street, Nanshan District, 518055 Shenzhen, PEOPLE'S
REPUBLIC OF CHINA

Product Category(ies): Ultrasonic Diagnostic System and Patient Monitor

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.:

GZ1922105

Valid from:

2020-02-11

Valid until:

2024-05-26

Date,

2020-02-11

Christoph Dicks
Head of Certification/Notified Body