Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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 051640 0008 Rev. 01

Manufacturer:

Shantou Institute of Ultrasonic Instruments Co., Ltd.
#77, Jinsha Road, Shantou, S.E.Z.
515041 Shantou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Shantou Institute of Ultrasonic Instruments Co., Ltd.
#77, Jinsha Road, Shantou, S.E.Z., 515041 Shantou, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Medical Ultrasonic Diagnostic Systems, DR Imaging 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.: SH18294EXT01

Valid from: 2019-02-20
Valid until: 2024-02-19

Date, 2018-12-03

Digitally signed by Jighili Tatiana
Date: 2019.08.08 10:45:24 EEST
Reason: MoldSign Signature
Location: Moldova

Stefan Preiß

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

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