



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 052731 0032 Rev. 00

Manufacturer:

**Xuzhou Kaixin Electronic Instrument
Co., Ltd.**

Kaixin Mansion
C-01, Economic Development Zone
221004 Xuzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Ultrasonic Diagnostic Instruments

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.:

SH2013401

Valid from:

2020-03-05

Valid until:

2024-05-26

Date,

2020-03-05

Christoph Dicks
Head of Certification/Notified Body



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