



Benannt durch/Designated by
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 053996 0012 Rev. 02

Manufacturer:

MEDA CO., LTD.

F2C, F3D, F4C, F5, F6C, Building C2
Xinmao Science Skill Park
Huayuan Industry Development Area
300384 Tianjin
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

MEDA CO., LTD.

F2C, F3D, F4C, F5, F6C, Building C2, Xinmao Science Skill Park,
Huayuan Industry Development Area, 300384 Tianjin, PEOPLE'S
REPUBLIC OF CHINA

Product Category(ies): Ultrasonic Biometer/Pachymeter for Ophthalmology, Ultrasonic A/B Scanner for Ophthalmology, Ultrasound Biomicroscope, Bladder Scanner.

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.:

BJ1987007

Valid from:

2019-07-09

Valid until:

2024-05-26

Date,

2019-07-09

Stefan Preiß

Head of Certification/Notified Body