



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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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 074184 0010 Rev. 00

Manufacturer:

SHENZHEN TAIJIA ELECTRONICS CO.,LTD.

5F, Building 20, 5 zone
Baiwangxin Industrial Park, Songbai Road
Nanshan District
518055 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

SHENZHEN TAIJIA ELECTRONICS CO.,LTD.
5F, Building 20, 5 zone, Baiwangxin Industrial Park, Songbai
Road, Nanshan District, 518055 Shenzhen, PEOPLE'S
REPUBLIC OF CHINA

SHENZHEN TAIJIA ELECTRONICS CO., LTD. BAOAN BRANCH
East Floor 4 & 7, Airmate Science & Technology Park, Huang
Feng Ling Industrial Zone, Shiyan Town, Baoan District, 518108
Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Pulse Oximeter Probes and Temperature Probes

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.:

GZ19005EXT01

Valid from:

2019-10-24

Valid until:

2024-05-26

Date,

2019-10-24

Stefan Preiß

Head of Certification/Notified Body