



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 085432 0004 Rev. 00

Manufacturer:

Shenzhen MedKe Technology Co., Ltd

4/F, Bldg.A1, Anle Ind. Zone, Hangcheng RD., Baoan Dist.,
518126 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Shenzhen MedKe Technology Co., Ltd
4/F, Bldg.A1, Anle Ind. Zone, Hangcheng RD., Baoan Dist.,
518126 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): SpO2 sensors

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.

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Stefan Preiß