





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 004717 0002 Rev. 00

Manufacturer: Shenzhen YKD Technology Co., Ltd.

6F, Building 6

Huaxinruiming Industrial Area

Langrong RD, Xinwei Village, Dalang Community

Dalang Street, Longhua 518000 Shenzhen

PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Shenzhen YKD Technology Co., Ltd.

6F, Building 6, Huaxinruiming Industrial Area, Langrong RD, Xinwei Village, Dalang Community, Dalang Street, Longhua, 518000 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Spo2 Sensor

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.: GZ1834801

 Valid from:
 2019-07-10

 Valid until:
 2024-05-26

Date, 2019-07-10

Stefan Preiß

1. Pumil

Head of Certification/Notified Body