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 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.

Report No.: GZ18114EXT01

Valid from: 2019-02-28
Valid until: 2024-01-16

Digitally signed by Matei Andrei
Date: 2022.03.24 13:18:25 EET
Reason: MoldSign Signature
Location: Moldova

Date, 2019-02-28

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
A4 / 07.17

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 085432 0005 Rev. 01

Holder of Certificate: **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

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Medical Compressors and Nebulizers system, Medical accessories (including SpO2 sensors, Temperature probes, Patient cables and Lead wires, BP accessories and Infusors)**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: GZ1911401

Valid from: 2020-02-17
Valid until: 2023-01-16

Date, 2020-02-17

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
A4 / 07.17