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 088955 0007 Rev. 01

Manufacturer: **Shenzhen Caremed Medical Technology Co.,Ltd.**
East side, 3/F, C building
Kelunte Low-carbon industries Park
Gaofeng community, Dalang offices
Longhua district
518109 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **SpO2 sensors, 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.: GZ1919201

Valid from: 2020-03-23
Valid until: 2024-05-26

Date, 2020-03-23

Christoph Dicks
Head of Certification/Notified Body

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

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

A4 / 07.17
Digitally signed by Volcovschi Mihai
Date: 2021.02.08 23:27:08 EET
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT ◆ ZERTIFIKAT

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

TÜV SÜD
Product Service

Certificate

No. Q5 088955 0005 Rev. 01

Applied Standard(s):

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

Facility(ies):

Shenzhen Caremed Medical Technology Co.,Ltd.
East side, 3/F, C building, Kelunte Low-carbon industries Park,
Gaofeng community, Dalang offices, Longhua district, 518109
Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Jiangxi Caremed Medical Technology Co., Ltd
Building 15th, Venture Incubator Park, Industrial Park District,
Xiajiang, 331400 Ji'an City, JiangXi Province, PEOPLE'S REPUBLIC OF CHINA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

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