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 093979 0005 Rev. 00

Manufacturer: **ShenZhen Medek Bio-Medical Co., Ltd.**
No.101 Wenhao Industrial Park
No.13 Yuanxin Road
Tongle Community, Baolong Street
Longgang District
518100 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): ShenZhen Medek Bio-Medical Co., Ltd.
No.101 Wenhao Industrial Park, No.13 Yuanxin Road, Tongle Community, Baolong Street, Longgang District, 518100 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Infrared Thermometer

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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Valid until: 2021-09-08

Date, 2018-08-09

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

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