



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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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.

**Report No.:**

GZ1821801

**Valid from:**

2018-08-09

**Valid until:**

2021-09-08

**Date,**

2018-08-09

Stefan Preiß

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT