INFRARED THERMOMETER

Specifications

Device name	Infrared thermometer
Model	MDI231
Measurement mode	Forehead mode / Ear mode
Power supply	d.c.3V , two 1.5 V type AAA (LR 03) batteries
Measurement site	Forehead / Ear
Measuring accuracy (At laboratory conditions)	±0.2°C / 0.4°F for 35.0°C-42.0°C(95.0°F-107.6°F) ±0.3°C / 0.5°F for other range
Clinical repeatability	within ±0.3°C
Resolution of display	0.1°C / 0.1°F
Operating environment	10.0°C-40.0°C(50.0°F-104°F)
What includes	Thermometer x 1 / User manual x 1

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

EC REP
Shanghai International Holding Corp. GmbH (Europe)
ADD: Eiffestrasse 80, 20537 Hamburg, GERMANY

CE 0123 MD

Made in China
Other details can be found in the manual.

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 093979 0007 Rev. 00

Manufacturer:

ShenZhen Medek Bio-Medical Co., Ltd.
No.101 Wenhao Industrial Park
No.13 Yuanxin Road
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Longgang District
518100 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer: CN-MF-000010426

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 093979 0007 Rev. 00

Report No.: GZ2121802

Valid from: 2022-07-25
Valid until: 2027-07-24

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-07-25

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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