



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. 01

Manufacturer:

ShenZhen Medek Bio-Medical Co., Ltd.

Room 3-502, Building T3
Haigu Technology Mansion
Luo Zu Community, Shiyan Street, Bao'an District
518108 Shenzhen, Guangdong
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, Certification, Validation and Verification Regulations 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. 01

Report No.:

GZ2421801

Preceding Certificate No.:

G10 093979 0007 Rev. 00

Valid from:

2024-09-06

Valid until:

2027-07-24

Date of Initial Issuance:

2022-07-25

Christoph Dicks

Head of Certification/Notified Body

Issue date: 2024-09-06



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Classification: Class IIa
Device Group: V030101 - THERMOMETERS
Intended Purpose: -

The validity of this certificate depends on conditions and/or is limited to the following: -none-

Revision History:

Rev.	Dated	Report	Description
00	2022-07-25	GZ2121802	-
01	2024-09-06	GZ2421801	Amended: Change of certificate holder's data Amended: Other