



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 103703 0006 Rev. 02

Manufacturer:

**Shenzhen AOJ Medical Technology
Co., Ltd.**

Room 301&4F, Block A, Building A
Jingfa Intelligent Manufacturing Park, Xiawei Yuan
Gushu Community, Xixiang Street
Bao'an District
518126 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000018386

Authorized Representative:

Share Info GmbH
Heerdter Lohweg 83, 40549 Düsseldorf, 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 103703 0006 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:G10_103703_0006_Rev.02)

Report No.: GZ2440502

Preceding Certificate No.: G10 103703 0006 Rev. 01

Valid from: 2025-02-19

Valid until: 2027-10-17

Date of Initial Issuance: 2022-10-18

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-02-19



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Classification:

Class IIa

Device Group:

V0301010201 - CONTACT DIGITAL THERMOMETERS
V0301010202 - NON-CONTACT DIGITAL THERMOMETERS
Z1203020408 - PULSE OXIMETERS
Z1203020501 - NON-INVASIVE OSCILLOMETRIC BLOOD
PRESSURE GAUGES

Intended Purpose:

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**The validity of this certificate
depends on conditions and/or
is limited to the following:**

-none-

Revision History:

Rev.	Dated	Report	Description
00	2022-10-18	GZ2240502	-
01	2024-05-22	GZ2340501, GZ2340501_ CN	Amended: Other Supplemented: Device(s)/group of device(s) added
02	2025-02-19	GZ2440502	Supplemented: Device(s)/group of device(s) added Supplemented: Other