UK Declaration of Conformity

According to the **Medical Devices Regulations 2002**

Manufacturer:	Shenzhen AOJ Medical Technology Co., Ltd
Address:	Room 301&4F, Block A, Building A, Jingfa Intelligent Manufacturing Park, Xiaweiyuan, Gushu Community, Xixiang Street, Bao'an District, 518126 Shenzhen, CHINA
	We hereby declare under our sole responsibility that the device specified is in conformity with the Medical Devices Regulations 2002 (SI 2002 No 618) as amended by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (SI 2020 No. 1478)
UK Responsible Person:	Share Info Ltd.
Address:	3rd Floor, Office C, Townend House, Park Street, Walsall, West Midlands, WS1 1NS, United Kingdom
Product Name:	Wrist Blood Pressure Monitor
Model:	AOJ-35A, AOJ-35B, AOJ-35C, AOJ-35D, AOJ-35E ,AOJ-35F,AOJ-35G,WRS-35E
Risk class:	Class IIa as defined by rule 10 of Annex IX of EU directive 93/42/EEC – as defined by UK regulation SI 2002 No 618, Part 2, regulation 7
Conformity assessment procedure:	Annex VII of Directive 93/42/EEC – as defined by UK regulation SI 2002 No 618, Part 2, regulation 13

Applied Standard(s):

EN ISO 14971:2019	EN ISO 13485:2016
ISO/TR 24971: 2020	IEC 60601-1:2005/A1:2012
IEC 62304:2006/A1:2015	EN 60601-1: 2006/A1:2013
ISO 20417:2021	IEC 60601-1-2:2014
IEC 62366-1:2015	EN IEC 60601-1-2: 2015
EN 14155:2020	ISO 15223-1:2021
EN ISO 10993-1:2020	IEC 60601-1-11:2015
EN ISO 10993-5:2009	IEC 80601-2-30: 2018
EN ISO 10993-10:2013	EN ISO 80601-2-30: 2019
EN 60601-1-6: 2010+A1:2015+A2:2020	

General manager: Jerry Gao

Place:

Date:

UK CA

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 103703 0006 Rev. 02

Manufacturer:

Shenzhen AOJ Medical Technology Co., Ltd.
Room 301&4F, Block A, Building A
Jingfa Intelligent Manufacturing Park, Xiaweiyuan
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

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

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

Benannt durch/Designated by
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BS-MDR-099

TÜV SÜD 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 103703 0006 Rev. 02

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:	-
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

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February 18, 2022

Shenzhen AOJ Medical Technology Co., Ltd.
Queena Chen
Regulatory Director
Room 301&4F, Blk A, Building A, Jingfa IM Park, Xiaweiyuan,
Gushu Community, Xixiang, Baoan
Shenzhen, Guangdong 518126
China

Re: K213503
Trade/Device Name: Wrist Blood Pressure Monitor, models AOJ-35A, AOJ-35B, AOJ-35C, AOJ-35D, AOJ-35E
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: December 20, 2021
Received: December 22, 2021

Dear Queena Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen C. Browning -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 103703 0004 Rev. 01

Holder of Certificate: **Shenzhen AOJ Medical Technology Co., Ltd.**
Room 301&4F, Block A, Building A
Jingfa Intelligent Manufacturing Park, Xiaweiyuan
Gushu Community, Xixiang Street
Bao'an District
518126 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Infrared Thermometer, Arm Blood Pressure Monitor, Wrist Blood Pressure Monitor, Pulse Oximeter and Digital Thermometer**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 103703 0004 Rev. 01

Report No.: GZ2240501

Valid from: 2023-01-15
Valid until: 2026-01-14

Date, 2022-12-13

Christoph Dicks
Head of Certification/Notified Body

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Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 103703 0004 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Shenzhen AOJ Medical Technology Co., Ltd.
Room 301&4F, Block A, Building A, Jingfa Intelligent Manufacturing Park, Xiaweiyuan, Gushu Community, Xixiang Street, Bao'an District, 518126 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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TEST REPORT

Report No.: DG5210604-21509E-M1 Date: July 22, 2021 Page 1 of 17

Shenzhen AOJ Medical Technology Co., Ltd.
Room 301&4F, Block A, Building A, Jingfa Intelligent Manufacturing Park, Xiaweiyuan, Gushu Community, Xixiang Street, Bao'an District, 518126 Shenzhen, PEOPLE' S REPULBIC OF CHINA

This report is to supersede test report No. DG5210604-21509E Date: July 21, 2021. The items used black in italics in the report was revised due to the applicant' s requirements.

Report on the submitted samples said to be:

Sample Name:	***Wrist Blood Pressure Monitor***
Style/Item No.:	AOJ-35A、AOJ-35B、AOJ-35C、AOJ-35D、AOJ-35E
Sample Receiving Date:	June 04,2021
Testing Period:	June 04,2021 - July 13,2021
Result:	Please refer to next page(s).

Signed for and on behalf of

BACL

Checked by: Jane Xu Approved by: Bensen Huang

TEST REPORT

Summary of Test Result:

TEST REQUEST	CONCLUSION
A RoHS Directive 2011/65/EU and its amendment directives (EU) 2015/863	Pass
A.1 XRF screening test	Please refer to next page(s).
A.2 Wet Chemical Testing	
A.2.1 Chromium VI (CrVI) content	Pass
A.2.2 PBBs & PBDEs content	Pass
A.3 Phthalates(DBP, BBP, DEHP, DIBP)content	Pass

FCC PART 18

TEST REPORT

For

Shenzhen AOJ Medical Technology Co., Ltd.

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

Test Model: AOJ-35B
Multiple Models: AOJ-35A, AOJ-35C, AOJ-35D, AOJ-35E

Report Type:	**Product Type:**
Original Report	Wrist Blood Pressure Monitor

Report Number:	DG5210721-30383E-00
Report Date:	2021-08-10
Reviewed By:	Redick Zhang EMC Engineer
Test Laboratory:	Bay Area Compliance Laboratories Corp. (Dongguan) No.12, Pulong East 1st Road, Tangxia Town, Dongguan, Guangdong, China Tel: +86-769-86858888 Fax: +86-769-86858891 www.baclcorp.com.cn

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