

EU Quality Management System Certificate FI23/1008001

The management system of

Shenzhen Yuezhongxing Technology Co., Ltd.

No. 2, Zhenye Road, Liulian Community, Pingshan Avenue, Pingshan District, Shenzhen, 518015, China
SRN: CN-MF-000024102

has been assessed and certified as meeting the requirements of

Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

For the following products

Blood Pressure Monitors

Certification is based on decision FI23/08123P0.

Previous certificate number: N/A

Change in between this certificate and previous one: N/A

Devices covered, risk classification, applied standards and applicable test and audit reports referred to, are listed on the subsequent pages of this certificate.

This certificate is valid from 24 August 2023 until 23 August 2028 and remains valid subject to satisfactory surveillance audits.

Issue 1 Certified since 24 August 2023

Certified activities performed by additional sites are listed on subsequent pages.



Authorised by

Seppo Vahasalo, NB Manager

SGS FIMKO OY

Notified Body 0598 Takomotie 8, FI-00380 Helsinki, Finland

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EU Quality Management System Certificate FI23/1008001, continued
Shenzhen Yuezhongxing Technology Co., Ltd.

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Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

Issue 1

Sites

Shenzhen Yuezhongxing Technology Co., Ltd.
No.2, Zhenye Road, Liulian Community, Pingshan Avenue, Pingshan District, Shenzhen, 518015,
China

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EU Quality Management System Certificate FI23/1008001, continued
Shenzhen Yuezhongxing Technology Co., Ltd.

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Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

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|--|-------------------|---|
| Attachment 1 of Issue 1 | | |
| | | |
| Device or Device Group, EMDN Code | Risk Class | Identification Details |
| Blood Pressure Monitors, C9006 ANEROID SPHYGMOMANO METERS | Ila | Arm Blood Pressure Monitor Models 111, B1681, B1682, B1683 |
| Blood Pressure Monitors, C9006 ANEROID SPHYGMOMANO METERS | Ila | Wrist Blood Pressure Monitor Models W202, W203, W1681 |
| The certification decision is based on the following: | | |
| Report Identification and Date | | |
| MDR-2019_Shenzhen Yuezhongxing_2023V1_FPMREG3019 - MD Audit Report Ver E - Rev.2, 2023-08-10 | | |
| MDR-2019_Shenzhen Yuezhongxing_2023V1_FPMREG3020 - MDR Technical Documentation Assessment Report Ver E, 2023-05-17 | | |
| Applied Standards / Common specifications | | |
| EN 60601-1:2006+A1:2013; EN 60601-1-2:2015; EN 60601-1-6:2010+A1:2015; EN 60601-1-11:2015; EN IEC 80601-2-30:2019; ISO 81060-2:2018; EN ISO 10993-1:2020; EN ISO 10993-5:2009; EN ISO 10993-10:2013; EN ISO 10993-23:2021; EN 62304:2006+A1:2015; EN 62366:2010+A1:2015; EN ISO 15223-1:2021 | | |
| Conditions for or limitation to the validity of the certificate | | |
| N/A | | |
| EU Authorised Representative | | |
| Kingsmead Service B.V, Zonnehof 36, 2632 BE, Nootdorp, Netherland SRN: NL-AR-000002066 | | |

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