

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

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 **FINAS**
Finnish Accreditation Service
S009 (EN ISO/IEC 17021-1)

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

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

Attachment 1 of Issue 1		
Device or Device Group, EMDN Code	Risk Class	Identification Details
Blood Pressure Monitors, C9006 ANEROID SPHYGMOMANO METERS	IIa	Arm Blood Pressure Monitor Models 111, B1681, B1682, B1683
Blood Pressure Monitors, C9006 ANEROID SPHYGMOMANO METERS	IIa	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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