

EU Declaration of Conformity

according to the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

This Declaration of Conformity is issued under the sole responsibility of the manufacturer. The device covered by the present Declaration is in conformity with REGULATION (EU) 2017/745 and related General Safety and Performance Requirements.

Manufacturer:		Shenzhen AOJ Medical Technology Co., Ltd.
Address:		Room 301&4F, Block A, Building A, Jingfa Intelligent Manufacturing Park, Xiaweyuan, Gushu Community, Xixiang Street, Bao'an District, 518126, Shenzhen, PEOPLE'S REPUBLIC OF CHINA
Single Registration Number (SRN) of the Manufacturer:		CN-MF-000018386
Authorised representative (AR):		Share Info GmbH
Address:		Am Schulzentrum 12,41564 Kaarst, Germany
Single Registration Number (SRN) of AR:		DE-AR-000005132
We, the manufacturer, declare under our sole responsibility that:		
the medical device(s)	Product Name:	Blood Pressure Monitor Cuff
	Type/model:	ARM-CUFF-M/ARM-CUFF-M-L/ARM-CUFF-M-XL
	EMDN Code:	V9099
	Intended Purpose:	The Blood pressure monitor cuff is compatible with most automatic upper-arm blood pressure monitors when using the existing air connector provided with the device.
	Classification:	Class I
Basic UDI-DI:		697204011ARM-CUFFLX
Conformity assessment procedure:		Annex II, Annex III
Harmonized standards and Common Specification:		<i>Refer to the Appendix I for details.</i>



Appendix I: Applied harmonized standards and Common Specification

is/are in conformity with the relevant provisions and requirements of the Council and the parliament regulation (EU) 2017/745 for medical device and all applicable harmonized standards and Common Specification. All supporting documents are retained under the premises of the manufacturer.

Applied harmonized standards and Common Specification

EN ISO 15223-1: 2021	EN ISO 10993-1: 2020
EN ISO 10993-5: 2009	EN ISO 10993-10: 2023
EN ISO 10993-23: 2021	EN ISO 13485: 2016 + A11:2021
EN 62366-1: 2015 + A1:2020	EN 60601-1-6:2010 + A1:2015 + A2:2021
EN ISO 20417: 2021	EN ISO 14971:2019 + A11:2021
EN ISO 780:2015	

This DoC is valid from 2024/11/26

Authorized by:


Jenny Geo

2025/02/19

Signature (on behalf of the manufacturer)

Position: Person responsible for regulatory compliance

Signed on: 2025/02/19

Place: Shenzhen, Guangdong, China

