

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:	AOJ HEALTH Technology Co., Ltd.		
Address:	Room 202, Building 5, Shuhe Industrial Park, Sanwei Community, Hangcheng Street, Bao'an District, 518126 Shenzhen. PEOPLE'S REPUBLIC OF CHINA		
Single Registration Number (SRN) of the Manufacturer:	CN-MF-000037449		
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:	Otoscope	
	Type/model:	OT-501, OT-503	
	EMDN Code:	Z12021009	
	Intended Purpose:	The otoscope is a handheld device equipped with lighting and a camera, intended to be used to observe the external ear, ear canal, and eardrum on a smartphone screen. Its secondary use is to provide general illumination of the throat and nasal passages by means of additional attachments.	
	Classification:	Class I	
	Basic UDI-DI:	697631375OTXW4	
Conformity assessment procedure:		Annex II, Annex III	
Harmonized standards and Common Specification:		Refer to the Appendix I for details.	

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 60601-1:2006 + A1:2013 + A2:2021	EN 60601-1-2:2015 + A1:2021
EN 60601-1-11:2015 + A1:2021	EN 60601-1-6:2010 + A1:2015 + A2:2021
EN 62366-1: 2015 + A1:2020	EN 62304:2006 + A1:2015
EN ISO 20417: 2021	EN ISO 14971:2019 + A11:2021
EN ISO 780:2015	

This DoC is valid from 2025/03/11

Authorized by:



JACK WANG

Signature (on behalf of the manufacturer)

Position: Person responsible for regulatory compliance

Signed on: 2025/03/11

Place: Shenzhen, Guangdong, China