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:		Building No.1, 1-3F, Building No.2, 2F, AOJ Industrial Park, Sanwei Community, Hangcheng Street, Bao'an District, Shenzhen 518126 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:**	OtoscopeOT-501 Accessories
	Type/model:	Nose speculum/Tongue depressor/Ear speculum
	Intended Purpose:	The nose speculum, tongue depressor, and ear speculum are accessories designed to be used with the Otoscope OT-501. They facilitate the examination of the nasal cavity, oral cavity, and ear canal, providing users with a more convenient and effective diagnostic experience.
	Classification:	Class I
	Basic UDI-DI:	697631375GIMAOT-501BQ
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:

Signature (on behalf of the manufacturer)

Position: Person responsible for regulatory compliance

Signed on:

Place: Shenzhen, Guangdong, China