

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 302, 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-000037449
Authorised representative (AR):	Share Info GmbH
Address:	Heerdter Lohweg 83, 40549 Düsseldorf, 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: Insect bite healer
	Type/model: IB 100, IB 200, IB 150, IB 80, IB A50, IB 50E, IBR10, IBR20, IBR30
	EMDN Code: V9099, VARIOUS DEVICES NOT INCLUDED IN OTHER CLASSES – OTHER
	Intended Purpose: The Insect bite healer is intended for relieving itching and swelling caused by insect bites or stings by applying heat (local hyperthermia).
	Classification: Class IIa Medical Device according to rule 9, Annex VIII
Basic UDI-DI:	697631375IBXTG
Conformity assessment procedure:	Annex IX chapter I
Harmonized standards and Common Specification:	<i>Refer to the Appendix I for details.</i>
Notified Body:	SGS FIMKO OY
Address:	Takomotie 8, FI-00380 HELSINKI, Finland
Notified Body number:	0598
Certificate(s) number.:	FI24/1008006
Expire date of the Certificate:	2026-03-17

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 14155:2020
EN ISO 780:2015	EN ISO 14971:2019 + A11:2021

This DoC is valid from

Authorized by:



Signature (on behalf of the manufacturer)

Position: Person responsible for regulatory compliance

Signed on: 2024.3.20

Place: Shenzhen, Guangdong, China