

# 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.

<b>Manufacturer:</b>	AOJ HEALTH Technology Co., Ltd.
<b>Address:</b>	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
<b>Single Registration Number (SRN) of the Manufacturer:</b>	CN-MF-000037449
<b>Authorised representative (AR):</b>	Share Info GmbH
<b>Address:</b>	Heerdter Lohweg 83, 40549 Düsseldorf, Germany
<b>Single Registration Number (SRN) of AR:</b>	DE-AR-000005132
<b>We, the manufacturer, declare under our sole responsibility that:</b>	
<b>the medical device(s)</b>	<b>Product Name:</b> Insect bite healer
	<b>Type/model:</b> IB 100, IB 200, IB 150, IB 80, IB A50, IB 50E, IBR10, IBR20, IBR30
	<b>EMDN Code:</b> V9099, VARIOUS DEVICES NOT INCLUDED IN OTHER CLASSES – OTHER
	<b>Intended Purpose:</b> The Insect bite healer is intended for relieving itching and swelling caused by insect bites or stings by applying heat (local hyperthermia).
	<b>Classification:</b> Class IIa Medical Device according to rule 9, Annex VIII
<b>Basic UDI-DI:</b>	697631375IBXTG
<b>Conformity assessment procedure:</b>	Annex IX chapter I
<b>Harmonized standards and Common Specification:</b>	<i>Refer to the Appendix I for details.</i>
<b>Notified Body:</b>	SGS FIMKO OY
<b>Address:</b>	Takomotie 8, FI-00380 HELSINKI, Finland
<b>Notified Body number:</b>	0598
<b>Certificate(s) number.:</b>	FI24/1008006
<b>Expire date of the Certificate:</b>	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:

*Jack Wang*

Signature (on behalf of the manufacturer)

Position: Person responsible for regulatory compliance

Signed on: 2024.3.20

Place: Shenzhen, Guangdong, China