### EU Quality Management System Certificate FI24/1008006

The management system of



# AOJ HEALTH Technology Co., Ltd.

Room 302, Block A, Building A, Jingfa Intelligent Manufacturing Park, Xiaweiyuan, Gushu Community, Xixiang Street, Bao'an District, 518126 Shenzhen, PEOPLE'S REPUBLIC OF CHINA SRN: CN-MF-000037449

has been assessed and certified as meeting the requirements of

### Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

For the following products Insect bite healers

Certification is based on decision FI24/08141P0

Previous certificate number: N/A

Change in between this certificate and previous one: N/A

Devices covered, their intended purposes, risk classification as well as applicable test and audit reports referred to, are listed on the subsequent pages of this certificate.

This certificate is valid from 18 March 2024 until 17 March 2026 and remains valid subject to satisfactory surveillance audits. Issue1. Certified since 18 March 2024

Certified activities performed by additional sites are listed on subsequent pages.

Authorised by

Seppo Vahasalo, NB

SGS FIMKO OY Notified Body 0598 Takomotie 8, FI-00380 Helsinki, Finland t +358 9 696 361 - www.sgs.fi



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## EU Quality Management System Certificate FI24/1008006, continued

# **AOJ HEALTH Technology Co., Ltd.**



## Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

Issue 1

#### **Sites**

Main site

Room 302, Block A, Building A, Jingfa Intelligent Manufacturing Park, Xiaweiyuan, Gushu Community, Xixiang Street, Bao'an District, 518126 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Headquarters, Administration, Design and Development, Sales

Room 202, Building 5, Shuhe Industrial Park, Sanwei Community, Hangcheng Street, Bao'an District, 518126 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Manufacturing, Inspection, Warehouse

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## EU Quality Management System Certificate FI24/1008006, continued





## Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

#### Attachment 1 of Issue 1

Device or Device Group,	Risk Class	Identification Details and Intended Purposes
MDA 0305	lla	Product: Insect Bite Healer
Active non-implantable		Model: IB 100, IB 200, IB 150, IB 80, IB A50, IB 50E, IBR10, IBR20, IBR30
devices for stimulation or		Intended purpose: The Insect Bite Healer is intended for relieving itching and swelling
inhibition		caused by insect bites or stings by applying heat (local hyperthermia).

The certification decision is based on the following:

#### Report Identification and Date

Medical Device Certification Audit Report, MDR-2054 FPMDREG3019-2023V1 - MD Audit Report Ver E\_Rev.1, dated 2023-12-25

Technical Documentation Assessment Report, MDR-2054\_FPMDREG3020 - MDR Technical Documentation Assessment Report Ver E Rev.2, dated 2024-03-01

#### Conditions for or limitation to the validity of the certificate

PMCF investigation is to be planned and conducted for Insect bite healer Model: IB 100, IB 200, IB 150, IB 80, IB A50, IB 50E, IBR10, IBR20, IBR30

#### **EU Authorised Representative**

Share info GmbH

Heerdter Lohweg 83, 40549 Düsseldorf, Germany

SRN: DE-AR-000005132

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