

## EU Quality Management System Certificate FI24/1008006

The quality management system of

# AOJ HEALTH Technology Co., Ltd.

Building No.1, 1-3F, Building No.2, 2F, AOJ Industrial Park Sanwei Community, Hangcheng Street, Bao'an District, Shenzhen, 518126, CHINA

SRN: CN-MF-000037449

### Regulation (EU) 2017/745 Annex IX (I and III)

for the following:  
Insect bite healers

#### Issue 4

Previous certificate's number and issue: FI24/1008006 Issue 3

Change in between this certificate and the previous one: Address change

The devices covered, their risk classifications, codes applied, identification details, intended purposes, standards and common specifications followed, conditions or limitations, 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 2026 until 17 March 2028 and remains valid subject to satisfactory surveillance audits.

Certified since 18 March 2024

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



Authorised by  
Jani Högman, Certifier

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EU Quality Management System Certificate FI24/1008006, continued

# AOJ HEALTH Technology Co., Ltd.



## Regulation (EU) 2017/745 Annex IX (I and III)

Issue 4
<b>Sites</b>
Main site Building No.1, 1-3F, Building No.2, 2F, AOJ Industrial Park, Sanwei Community, Hangcheng Street, Bao'an District, Shenzhen 518126 CHINA
Administration, Design and Development, Sales, Manufacturing, Inspection, Warehouse

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**Regulation (EU) 2017/745 Annex IX (I and III)**

<b>Attachment 1 of Issue 4</b>
<b>Risk classes, codes, identification, and other relevant details of the certified devices:</b> Risk class IIa MDA 0305, MDT2010, MDT2011 EMDN V9099 Various Devices Not Included in Other Classes - Other Insect bite healer Model: IB 50E, IBR70, IBR75, IBR80, Basic UDI-DI:697631375IBXTG Model: BR 70, BR 75, BR 100, BR 200, Basic UDI-DI:697631375IBXTG Model: IBR600, IBR700, IBR800, IBR900, Basic UDI-DI:697631375IBXTG Model: IB 100, IB 200, IB 150, IB 80, IB A50, IB 50E, IBR10, IBR20, IBR30, IBR40, IBR50, IBR60, Basic UDI-DI:697631375IBXTG, Intended use: The Insect bite healer is intended for relieving itching and swelling caused by mosquito bites by applying heat (local hyperthermia).
<b>The certification decision is based on the following:</b> <b>Report Identification and Date:</b> Audit report: MDR-2054_2025V3_FPMDREG3019 - MD Audit Report Ver G 2026-02-28 , dated 2026-02-28 Technical documentation assessment reports: MDR-2054_2025V3_FPMDREG3020 - MDR Technical Documentation Assessment Report Ver H 2026-02-28, dated 2026-02-28  <b>Applied Standards / Common specifications:</b> EN ISO 13485:2016 + A11/2021, EN ISO 14971:2019 + A11/2021, EN ISO 15223-1:2021, references to other relevant CS and harmonized standards are in the reports  <b>Conditions for or limitation to the validity of the certificate:</b> N/A  <b>EU Authorised Representative:</b> Share info GmbH Am Schulzentrum 12, 41564 Kaarst, Germany SRN: DE-AR-000005132

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