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
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FINAS
Finnish Accreditation Service
S009 (EN ISO/IEC 17021-1)

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

AOJ HEALTH Technology Co., Ltd.

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 Active non-implantable devices for stimulation or inhibition	IIa	Product: Insect Bite Healer Model: IB 100, IB 200, IB 150, IB 80, IB A50, IB 50E, IBR10, IBR20, IBR30 Intended purpose: The Insect Bite Healer is intended for relieving itching and swelling 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