

EU Quality Management System Certificate FI25/1008012

The management system of

Xiamen Weiyou Intelligent Technology Co., Ltd

Unit 301, No. 6 Xianghong Road, Torch Hi-Tech Zone Industrial Park, Xiang'an District, Xiamen, P.R.China

SRN: CN-MF-000028653

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 and activities

Air Pressure Therapy Systems

Issue 2

Previous certificate's number and issue: FI25/1008012

Change in between this certificate and the previous one: EU Authorised Representative 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 10 October 2025 until 03 April 2027 and remains valid subject to satisfactory surveillance audits.

Certified since 04 April 2025

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



Authorised by
Seppo Vahasalo, NB Manager

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)

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EU Quality Management System Certificate FI25/1008012, continued



Xiamen Weiyou Intelligent Technology Co., Ltd

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

Issue 2
Sites
Unit 301, No. 6 Xianghong Road, Torch Hi-Tech Zone Industrial Park, Xiang'an District, Xiamen, P.R.China
Air Pressure Therapy Systems

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Xiamen Weiyou Intelligent Technology Co., Ltd

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

Attachment 1 of Issue 2

Risk classes, codes, identification, and other relevant details of the certified devices:

Risk IIa

Air Pressure Therapy System, class IIa
EMDN Z120607 pneumatic compression equipment
MDA 0318, MDT 2010, MDT 2011

Models: VU-IPC01, VU-IPC02, VU-IPC03, VU-IPC04B, VU-IPCA8, VU-IPCU8

Basic UDI-DI:

697123447VU-IPC017K, 697123447VU-IPC027M, 697123447VU-IPC037P, 697123447VU-IPC04BM5,
697123447VU-IPCA89H, 697123447VU-IPCU8BD

Models: VU-NIPC02, VU-IPC04, VU-IPC06

Basic UDI-DI:

697123447VU-NIPC02R4, 697123447VU-IPC047R, 697123447VU-IPC067V

The certification decision is based on the following:

Report Identification and Date:

Xiamen Weiyou_FPMDREG1036 - MDR Application review report Ver G-NOC
XiamenWeiyou-FPMDREG1007 - MDR Notification of QMS Changes and Regulatory Actions Ver K-2025-08-01-Reviewed-2025-08-13

Applied Standards / Common specifications:

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

Conditions for or limitation to the validity of the certificate:

Manufacturer is required to plan and conduct a PMCF-study recruiting an adequate number of patients with endpoints targeted to confirm the conclusions of long-term safety and effectiveness of the devices.

EU Authorised Representative:

SUNGO Cert GmbH, Harffstr. 47,40591 Düsseldorf, Germany SRN: DE-AR-000010869