

EC Certificate Production Quality Assurance System FI20/07010

The management system of

## Aiamen Weiyou Intelligent Technology

The second East Factory, 215-219 Tian Feng road, Xiamen P.R.China

has been assessed and certified as meeting the requirements of

## **Directive 93/42/EEC**

on Medical Devices, Annex V

For the following products
Air Pressure Therapy Systems

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 06 May 2020 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 06 May 2020
This certification is based on decision: FI20/07011P0

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

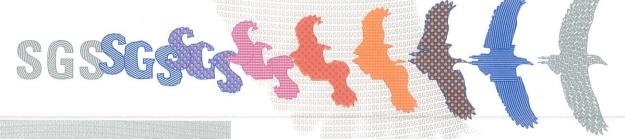
Authorised by

Seppo Vahasalo Notified Body Manager

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## Attachment 1 to SGS Fimko Ltd. EC certificate Fl20/07010 Issue 1

Manufacturer	Xiamen Weiyou Intelligent Technology Co., Ltd	
Address	The second East Factory, 215-219 Tian Feng road, Xiamen, P.R.China	
Activity and Medical Device Product Category	93/42/EEC Annex V Air Pressure Therapy Systems	

List of medical devices and the corresponding type/model markings with product trademarks/marketing names covered by this certificate:

Medical Device	Class	Trademark(s) and Model(s)/type(s)
Air Pressure Therapy Systems	lla	VU-IPC04
Air Pressure Therapy Systems	lla	VU-IPC06
Air Pressure Therapy Systems	lla	VU-NIPC02

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06 May 2020

**DECISION** 

FI20/07011P0



Xiamen Weiyou Intelligent Technology Co., Ltd The second East Factory, 215-219 Tian Feng road, Xiamen P.R.China

EC-certification application 18/090-1 dated 2020-04-14, updated from 18/090-0 dated 2018-06-01.

Subject

Certification of quality system and product range, based on Council Directive

93/42/EEC concerning medical devices, Annex V Section 3.

Manufacturer

Xiamen Weiyou Intelligent Technology Co., Ltd

The second East Factory, 215-219 Tian Feng road, Xiamen

P.R.China

Decision

A certificate will be issued for the manufacturer. The certificate covers the

following products:

Product

Model

Class

Air Pressure Therapy

VU-IPC04, VU-IPC06, VU-

lla

Systems

NIPC02

Justification

SGS Fimko Ltd has assessed manufacturer's quality management system and products. Quality management system and products meet the requirements of Annex V of Medical Device Directive 93/42/EEC. The decision

is based on audit and technical file review report(s) 292522, dated 6 Nov.

2019

The manufacturer has signed the undertaking to follow the obligations of

Annex V of the Directive 93/42/EEC.

Certificate related to decision

FI20/07010, issue1

Attachment to certificate

Attachment 1,

Valid until

This decision is valid until 24 May 2024 providing the requirements of the

certification are fulfilled.

Date

Helsinki, 06 May 2020

Seppo Vahasalo, Notified Body Manager

SGS Fimko Ltd, Notified Body 0598