EC Certificate Production Quality Assurance System FI20/07010

The management system of

Xiamen Weiyou Intelligent Technology Co., Ltd

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 FI20/07010 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	IIa	VU-IPC04
Air Pressure Therapy Systems	IIa	VU-IPC06
Air Pressure Therapy Systems	IIa	VU-NIPC02

DECISION

06 May 2020

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 Systems	VU-IPC04, VU-IPC06, VU-NIPC02	IIa

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