SGS

EC Certificate Production Quality Assurance System FI20/07010

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

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 02 April 2021 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 06 May 2020

This certification is based on decision: FI21/07032P0

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

Authorised by

Jani Högman Certifier

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Attachment 1 to SGS Fimko Ltd. EC certificate FI20/07010 Issue 2

Manufacturer	Xiamen Weiyou Intelligent Technology Co., Ltd		
Address	Unit 301, No. 6 Xianghong Road, Torch Hi-Tech Zone Industrial Park, Xiang'an District, 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	PARTY TO THE PARTY OF THE PARTY		
	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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02 April 2021

DECISION

FI21/07032P0



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

EC-certification application 18/090-2, dated 2020-09-30

Subject

Certification of quality system and product range, due change of manufacturers address, based on Council Directive 93/42/EEC concerning medical devices, Annex V Section 3.

Manufacturer

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

Decision

A certificate will be issued for the manufacturer. The certificate covers the following products:

Product
Air Pressure Therapy
Systems

WU-IPC04, VU-IPC06, VU-NIPC02 Class

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 Report(s) 292522, dated 22 Feb. 2021.

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, issue 2

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, 02 April 2021

Jani Högman, Certifier

SGS Fimko Ltd, Notified Body 0598