EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Shenzhen Fitfaith Technology Co., Ltd

Main Site: Area B, Floor 9, Building D1, Tangwei Industrial Park, Donglong Road, Guangming New District, Shenzhen City, Guangdong Province, P.R. China

Digitally signed by Belan Irina
Date: 2021.07.06 09:08:10 EEST
Reason: MoldSign Signature
Location: Moldova

Product Category:

- Pulse Oximeters and Sensors

For further identification of the products covered, see the MDD product list/product schedule.

*Previously certified by Intertek AMTAC (NB0473) to date 26 January 2018

Certificate Number:
41371470-02

Initial Certification Date:
26 January 2018*

Certificate Valid from:
8 May 2020

Certificate Expiry Date:
26 May 2024

SWEDAC ACKREDITERING
Accred. no. 1003
Certification of Management Systems
ISO/IEC 17021-1

Bob Andersson
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

8 May 2020
Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

MDD – Product List

Products included in the certificate no: 41371470-02

Issued to: **Shenzhen Fitfaith Technology Co., Ltd**
Area B, Floor 9, Building D1, Tangwei Industrial Park, Donglong Road, Guangming New District, Shenzhen City, Guangdong Province, P.R. China

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Pulse Oximeters and Sensors					
	Handheld Pulse Oximeter F380	IIa	No		Jan 26, 2018
	Handheld Pulse Oximeter F380A	IIa	No		Jan 26, 2018
	Finger Pulse Oximeter M100	IIa	No		Jan 26, 2018
	Finger Pulse Oximeter M110	IIa	No		Jan 26, 2018
	Finger Pulse Oximeter M120	IIa	No		Jan 26, 2018
	Finger Pulse Oximeter M130	IIa	No		Jan 26, 2018
	Finger Pulse Oximeter M150	IIa	No		Jan 26, 2018
	Finger Pulse Oximeter M160	IIa	No		Jan 26, 2018
	Finger Pulse Oximeter M170	IIa	No		Jan 26, 2018
	Sensors - S901	IIa	No		Jan 26, 2018
	Sensors - S901B	IIa	No		Jan 26, 2018
	Sensors - S902	IIa	No		Jan 26, 2018
	Sensors - S903	IIa	No		Jan 26, 2018
	Sensors - S904	IIa	No		Jan 26, 2018
	Sensors - S905	IIa	No		Jan 26, 2018

Date of Issue: 8 May 2020

Intertek Semko AB
Notified Body MDD

Bob Andersson
Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

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Intertek Semko AB
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Registered in Sweden: No SE556024059901, Registered office: As address

MDD – Decision Report

Certificate No: 41371470-02
Date: 8 May 2020
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

Shenzhen Fitfaith Technology Co., Ltd
Attn: Lili Liu
Area B, Floor 9, Building D1, Tangwei Industrial Park, Donglong Road,
Guangming New District, Shenzhen City, Guangdong Province,
P.R. China

Purpose	Assessment to issue a new certificate due to early five year extension according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II.
Activity	Certification audit was performed 11 April 2020 in Shenzhen City by Cicy Xiong Qian and Heidi Cai Hongbo. The technical file was reviewed 4 May 2020 by Abul Kashem at Intertek's office.
Scope of assessment	Pulse Oximeters and Sensors, Class IIa
Result	1 minor non conformities were noted during the audit. Presented corrective action plans have been examined and approved by us.
Certificate Valid from	8 May 2020
Conclusions/Decisions	Referring to the above a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II will be issued. The Certificate is valid for products specified in the "MDD – Product List".
Follow-up assessments	Follow-up assessments are going to be performed once a year.
Appeals	Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.
Others	Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Semko has the right to review this documentation.

Intertek Semko AB
Notified Body MDD

Bob Andersson
Certification Authority MDD