DECLARATION OF CONFORMITY

TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993

CONCERNING MEDICAL DEVICES

Version 1.5 MS-CE-04

MANUFACTURER: SHENZHEN FITFAITH TECHNOLOGY CO., LTD.

AREA B, FLOOR 9, BUIDING D1, TANGWEI INDUSTRIAL PARK, DONGLONG ROAD, GUANGMING NEW DISTRICT, SHENZHEN, PRC

EUROPEAN REPRESENTATIVE: LOTUS NL B.V.

KONINGIN JULIANAPLEIN 10, 1E VERD, 2595AA, THE HAGUE, NETHERLANDS.

PRODUCT: PULSE OXIMETER M100,M110,M120,M130,M150,M160,M170

CLASSIFICATION: CLASS II A, RULE 10 ACCORDING TO ANNEX IX OF THE MDD 93/42/EEC

CONFORMITY ASSESSMENT ROUTE: ANNEX II

WE HEREBY DECLARE THAT THE ABOVE MENTIONED DEVICES COMPLY WITH THE LEGISLATION OF THE SWEDISH NATIONAL LEGISLATION LVFS 2003:11 TRANSPOSING ANNEX II OF THE DIRECTIVE 93/42/EEC ON MEDICAL DEVICES ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: SEE ATTACHED LIST OF STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.

NOTIFIED BODY: INTERTEK SEMKO AB, TORSHAMNSGATAN 43, BOX 1103, SE-164 22 KISTA, SWEDEN

IDENTIFICATION NUMBER: CE 0413

(EC) CERTIFICATE(S): 41371470-02

START OF CE-MARKING: 8 MAY 2020

PLACE, DATE OF ISSUE: SHENZHEN, CHINA, 8 MAY 2020

SIGNATURE: _____

(YUAN JUNFENG) GENERAL MANAGER

ATTACHED: LIST OF STANDARDS

#	No./Edition	Standards Title
1	MDD 93/42/EEC &2007/47/EC	COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993concerning medical devices
2	EN ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
3	EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
4	EN 60601-1:2006/A1:2013	Medical electrical equipment -Part 1:General requirements for basic safety and essential performance
5	EN 60601-1-2:2015	Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral Standard: Electromagnetic disturbances – Requirements and tests
6	EN ISO 80601-2-61:2019	Medical electrical equipment —Part 2-61: Particular requirements for the basic safety and essential performance of pulse oximeter equipment
7	EN60601-1-11:2015	Medical electrical Equipment-Part 1-11:General requirements for basic safety and essential Performance-Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
8	EN ISO 15223-1: 2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
9	EN 1041: 2008+A1: 2013	Information supplied by the manufacturer with medical devices
10	EN 62304: 2006+A1: 2015	Medical device software - Software life cycle processes
11	EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
12	EN ISO 10993-1:2009	Biological evaluation of medical device- part 1: Evaluation and testing
13	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5:Tests for in vitro cytotoxicity.
14	EN ISO 10993-10:2010	Biological evaluation of medical devices -Part 10:Tests for irritation and delayed-type hypersensitivity.
15	MEDDEV2.7.1: 2016 rev.4	Clinical evaluation: a guide for manufacture and notified bodies

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

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