intertek
Total Quality. Assured.

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

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.

Certificate Number:
41371470

Initial Certification Date:
January 26, 2018

Certificate Valid from:
January 26, 2018

Certificate Expiry Date:
January 25, 2023

SWEDAC ACKREDITERING
Ackred. nr 1003
ISO/IEC 17021

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

January 26, 2018
Signed Date

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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.