DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993
CONCERNING MEDICAL DEVICES

Version 1.0 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 GLOBAL CO.,LTD.

1 FOUR SEASONS TERRACE WEST DRAYTON, MIDDLESEX LONDON, UB7 9GG UNITED KINGDOM

PRODUCT: HANDHELD PULSE OXIMETER F380

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

CONFORMITY ASSESSMENT ROUTE: ANNEX V.3

WE HEREBY DECLARE THAT THE ABOVE MENTIONED DEVICES COMPLY WITH THE LEGISLATION OF MEMBER STATES AT DAVY AVENUE, KNOWLHILL MILTON KEYNES MK5 8NL, UNITED KINGDOM TRANSPOSING EUROPEAN MEDICAL DEVICE DIRECTIVE 93/42/EEC. 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: AMTAC CERTIFICATION SERVICES LTD

IDENTIFICATION NUMBER: CE 0413

(EC) CERTIFICATE(S):

START OF CE-MARKING:

PLACE, DATE OF ISSUE:

SIGNATURE: 原峻峰（YUAN JUNFENG） GENERAL MANAGER

ATTACHED: *LIST OF STANDARDS*

1. 93/42/EEC
2. EN ISO13485:2012
3. IEC 60601-1: 2005+A1:2012
4. ISO 80601-2-61:2011
5. EN ISO14971:2012
6. IEC 60601-1-2: 2007
7. EN ISO 10993-1:2009
8. EN ISO 10993-5:2009
9. ISO10993-10:2010
10. EN980:2008，
11. EN1401:2008
12. EN 62304:2006
13. EN 62366: 2008

For and on behalf of

深圳市华信康科技有限公司

Shenzhen Fitfaith Technology Co.,Ltd

.....Daniel Shi.....

Authorized Signature(s)