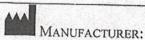
DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES



Hunan Accurate Bio-Medical Technology Co., Ltd., Floor, Biyang Industrial Zone, Lijiacun Road, Xueshi Street of Yuelu District, 410208 Changsha, Hunan Province, PEOPLE'S REPUBLIC OF CHINA (85300)

MEDICAL DEVICE:

PULSE OXIMETER

MODEL: FS10A, FS20A, FS10B, FS20B,FS10C,FS20C,FS10D. FS20D, FS10E, FS20E, FS10F, FS20F, FS10I,FS20I,FS10K, FS20K,FS10P,FS20P

CLASSIFICATION - ANNEX IX:

CLASS IIa, RULE 10

CONFORMITY ASSESSMENT ROUTE: .ANNEX II (EXCLUDE II.4)

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES;

INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER. WE ARE EXCLUSIVELY RESPONSIBLE FOR THIS DOC.

STANDARDS APPLIED: EN 60601-1:2006/A1:2013 ,EN 60601-1-2:2015,ISO 80601-2-61:2011,EN ISO 15223-1:2016,EN 1041:2016,EN ISO 14971:2012,EN ISO10993-1:2009/AC2010,EN ISO10993-5:2009,EN ISO 10993-10:2010, EN 62304:2006+A1:2015, EN 60601 - 1-6:2010/A1:2015.

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH

RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER

0123

(EC) CERTIFICATE(S):

G1 085300 0008 Rev.01

EC REP EUROPEAN REPRESENTATIVE:

Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, 20537 Hamburg, Germany

START OF CE-MARKING:

2019-05-15

PLACE, DATE OF DECLARATION:

CHANG SHA, 2019-08-12

SIGNATURE:

POSITION: GENERAL MANAGER

