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

MANUFACTURER: Hunan Accurate Bio-Medical Technology Co., Ltd., 6th 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: CHANGSHA, *2019-08-12*

SIGNATURE: ZHANG LI

NAME: ZHANG LI
POSITION: GENERAL MANAGER