

**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



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:

ZHANG LI  
NAME: ZHANG LI  
POSITION: GENERAL MANAGER