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,HS10A,HS20A,FS10C FS20C,FS10D,FS20D,FS10E,FS20E,FS10I,FS20P
CLASSIFICATION - *ANNEX IX*: **CLASS IIB, RULE 10**

CONFORMITY ASSESSMENT ROUTE: **ANNEX II.3**

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.

STANDARDS APPLIED: ***IEC60601-1:2005,EN60601-1-2:2014,ISO80601-2-61:2017,EN980:2008,EN1041:2008,EN ISO 14971:2012,EN ISO10993-1:2009/AC2010,EN ISO10993-5:2009,EN ISO 10993-10:2010, EN62304:2006, EN 60601-1-6:2010.***

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 M NCHEN, GERMANY

IDENTIFICATION NUMBER CE 0123

(EC) CERTIFICATE(S): G1 085300 0008 REV.00

EC REP
EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg，Germany

START OF CE-MARKING: 2013-10-10

PLACE, DATE OF DECLARATION: HUNAN, 2018-9-1

SIGNATURE: NAME: _____
POSITION: GENERAL MANAGER

Ref: EN ISO/IEC 17050-1