

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



MANUFACTURER: HUAN ACCURATE BIO-MEDICAL TECHNOLOGY CO.,LTD
M8-613, No.8, LUTIAN ROAD, CHANGSHA NATIONAL HI-TECH INDUSTRIAL
DEVELOPMENT ZONE, CHANGSHA, HUNAN PROVINCE, P.R. CHINA

MEDICAL DEVICE: PULSE OXIMETER MODEL: FS10A, FS20A, HS10A, HS20A

CLASSIFICATION - *ANNEX IX*: **CLASS IIB, RULE 10**

CONFORMITY ASSESSMENT ROUTE: **ANNEX II + V.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. PULSE OXIMETER FULFILS THE REQUIREMENTS OF THE HARMONIZED TECHNICAL NORMS WHICH WERE USED FOR ASSESSING OF CONFORMITY: ISO80601-2-61:2011.

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

START OF CE-MARKING: **2014-9-10**

PLACE, DATE OF DECLARATION: CHANGSHA, SEPTEMBER 10, 2014

SIGNATURE:

NAME: 
POSITION: GENERAL MANAGER