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

SHENZHEN BIOCARE BIO-MEDICAL EQUIPMENT CO., LTD.
#16-1，JINHUI ROAD, JINSHA COMMUNITY, KENGZI SUB-DISTRICT, PINGSHAN NEW DISTRICT, 518122 SHENZHEN, PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE:	*DIGITAL ELECTROCARDIOGRAPH* *TYPE: iE 3, iE 6* *GMDN CODE:16231*
CLASSIFICATION - *ANNEX IX*:	*CLASS IIA, RULE 10*
CONFORMITY ASSESSMENT ROUTE:	*ANNEX II EXCLUDING(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 CONCERNING MEDICAL DEVICES;
INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC AND INCLUDING REQUIREMENTS FROM OF MDR ARTICLE 120 (3) AFTER MAY 26TH 2021.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DOC.

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH Ridlerstraße 65 · 80339 Munich · Germany
IDENTIFICATION NUMBER	CE 0123
(EC) CERTIFICATE(S):	*G1 065758 0004 REV.01*
EC REP EUROPEAN REPRESENTATIVE:	*SHANGHAI INTERNATIONAL HOLDING CORP. GMBH (EUROPE)* *Eiffestraße 80, 20537 Hamburg, GERMANY*

START OF CE-MARKING: *2017-05-20*

PLACE, DATE OF DECLARATION:	*SHENZHEN P.R.C., 2023-09-12*
SIGNATURE:	_____ *NAME:CHENJUN* *POSITION: GENERAL MANAGER*