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

MANUFACTURER: *SHENZHEN BIOCARE BIO-MEDICAL EQUIPMENT CO., LTD.*
HEADQUARTER ADDRESS.: #A735, 7/F, BLOCK A, SHENZHEN MINGYOU INDUSTRIAL PRODUCTS EXHIBITION & PROCUREMENT CENTER, BAOYUAN ROAD, XIXIANG SUB-DISTRICT, BAO'AN DISTRICT, 518102 SHENZHEN, PEOPLE'S REPUBLIC OF CHINA.
FACTORY ADDRESS.: 2/F WEST, 4TH BLOCK DAYANG ROAD SOUTH, FUYONG SUB-DISTRICT, BAO'AN DISTRICT, 518103 SHENZHEN, PEOPLE'S REPUBLIC OF CHINA.

MEDICAL DEVICE:	*DIGITAL ELECTROCARDIOGRAPH* *TYPE:* iE 3, iE 6 *GMDN CODE: 11407*
CLASSIFICATION - *ANNEX IX*:	*CLASS IIA, 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 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.

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER	CE 0123
(EC) CERTIFICATE(S):	*G1 15 01 45163 023*
EC REP EUROPEAN REPRESENTATIVE:	*SHANGHAI INTERNATIONAL HOLDING CORP. GMBH (EUROPE)* *Eiffestraße 80, 20537 HAMBURG, GERMANY*

START OF CE-MARKING: 2013-09-10

PLACE, DATE OF DECLARATION:	*SHENZHEN P.R.C., 2015*-03-31
SIGNATURE:	_____ *NAME:* *POSITION: GENERAL MANAGER*