

## 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.  
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



(EC) CERTIFICATE(S): *G1 065758 0004 REV.01*



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., 2019-09-19*

SIGNATURE:

NAME: CHENJUN  
POSITION: GENERAL MANAGER