

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 101, iE 300
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

CE 0123

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

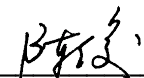


EUROPEAN REPRESENTATIVE: *SHANGHAI INTERNATIONAL HOLDING CORP. GMBH
(EUROPE)
Eiffestraße 80, 20537 Hamburg, GERMANY*

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

PLACE, DATE OF DECLARATION: *SHENZHEN P.R.C., 2019-09-19*

SIGNATURE:


NAME: CHENJUN
POSITION: GENERAL MANAGER