

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*

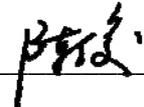


EUROPEAN REPRESENTATIVE: *SHANGHAI INTERNATIONAL HOLDING CORP. GMBH*
(EUROPE)
Eiffestraße 80, 20537 HAMBURG, GERMANY

START OF CE-MARKING: 2013-09-10

PLACE, DATE OF DECLARATION: *SHENZHEN P.R.C., 2015-03-31*

SIGNATURE:


NAME:

POSITION: *GENERAL MANAGER*