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	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., 2019-09-19*

SIGNATURE: _____

NAME:CHENJUN
POSITION: GENERAL MANAGER

Digitally signed by Potînga Stela
Date: 2024.03.20 08:56:44 EET
Reason: MoldSign Signature
Location: Moldova