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

MANUFACTURER: Beijing Safe Heart Technology Ltd.
Room 101, Unit 6, Building No.6, No.88 Kechuang 6th Street, Beijing
Economic-Technological Development Area, 101111 Beijing, P. R. China

MEDICAL DEVICE: Pulse Oximeter
TYPE:SHO-3002 (HbO-2000) SHO-5002 (HbO-3000)

CLASSIFICATION - *ANNEX IX*: *E.G. CLASS IIA, RULE 10*

CONFORMITY ASSESSMENT ROUTE: *E.G. 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 OF 14 JUNE 1993 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. A STATEMENT THAT THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DOC.

STANDARDS APPLIED: *SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED. (NOTE: IT IS SUGGESTED THAT THIS LIST STATE THE STANDARDS' FULL NAME AND DATE OF ISSUE AND INCLUDES ALL AMENDMENTS. A CROSS REFERENCE TO THIS STANDARDS LIST FROM THE ESSENTIAL REQUIREMENTS CHECKLIST MINIMISES DOCUMENT CHANGES IN THE EVENT OF STANDARDS RE-ISSUE OR AMENDMENT).*

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 M NCHEN, GERMANY

IDENTIFICATION NUMBER 0123

(EC) CERTIFICATE(S): *G1 087949 0002*
SHOW ONLY THE EC CERTS WITH A SCOPE THAT COVERS THE PRODUCTS LISTED

EC REP
EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg , Germany

START OF CE-MARKING: *2014-07-03*

PLACE, DATE OF DECLARATION: *CITY, DATE*

SIGNATURE: 2014.7.4.

NAME: MR. ZHIQIANG TI
POSITION: QMR