

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 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER

0123

(EC) CERTIFICATE(S):

G1 087949 0002

SHOW ONLY THE EC CERTS WITH A SCOPE THAT COVERS THE PRODUCTS LISTED



EUROPEAN REPRESENTATIVE:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

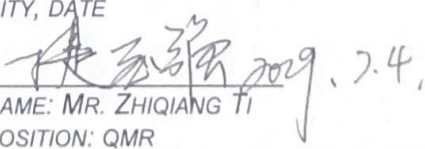
START OF CE-MARKING:

2014-07-03

PLACE, DATE OF DECLARATION:

CITY, DATE

SIGNATURE:


NAME: MR. ZHIQIANG TI
POSITION: QMR