

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



MANUFACTURER: TIANJIN SUOWEI ELECTRONIC TECHNOLOGY CO., LTD.

ADDRESS: ROOM 2-201, 2#BUILDING, NO.6, ZHUYUAN ROAD, HUAYUAN INDUSTRIAL ZONE,
300384 TIANJIN, PEOPLE'S REPUBLIC OF CHINA.

MEDICAL DEVICE: TONOMETER

TYPE: SW-500

UMDNS CODES: 11389

CLASSIFICATION - ANNEX IX: MDDIIA

CONFORMITY ASSESSMENT ROUTE: ANNEX II, ITEM 3

WE, TIANJIN SUOWEI ELECTRONIC TECHNOLOGY CO., LTD., HEREWITH DECLARE THAT THE
STATED MEDICAL DEVICES MEET THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING
MEDICAL DEVICES;

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: EN ISO 13485:2012; EN 60601-1:2006; EN 60601-1-2:2007; EN 60601-1-6:2010; EN
60601-2-37:2008;; EN 61157:2007; EN ISO 14971:2012; EN ISO 14155:2011; EN ISO 10993-1:2009; EN ISO
10993-5:2009; EN ISO 10993-10:2010; EN 62366:2008; EN 62304:2006; EN ISO 15004-1:2009; EN
980:2008; EN 1041:2008.

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER

 0123

(EC) CERTIFICATE(S):

No. G1 14 08 60982 008

EC REP

EUROPEAN REPRESENTATIVE:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse, 80, 20537, Hamburg, Germany
Tel: 0049-40- 2513175, Fax: 0049-40-255726

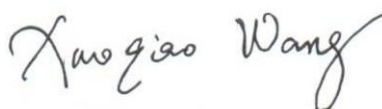
START OF CE-MARKING:

2011-04-14

PLACE, DATE OF DECLARATION:

TIANJIN, 2015-11-03

SIGNATURE:



NAME: XUEQIAO WANG

POSITION: GENERAL MANAGER