

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



TIANJIN SUOWEI ELECTRONIC TECHNOLOGY CO., LTD.  
2#BUILDING, No.6, ZHUYUAN ROAD, HUAYUAN INDUSTRIAL ZONE, 300384 TIANJIN, PEOPLE'S  
REPUBLIC OF CHINA.

MEDICAL DEVICE: REBOUND TONOMETER      **TYPE:** SW-500      **UMDNS CODES:** **14068**

CLASSIFICATION - ANNEX IX:      **CLASS IIA, RULE 10**

CONFORMITY ASSESSMENT ROUTE:      **ANNEX II(EXCLUDING SECTION 4)**

WE, TIANJIN SUOWEI ELECTRONIC TECHNOLOGY CO., LTD., 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 MANUFACTURE.  
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DoC.

STANDARDS APPLIED: **EN ISO 13485:2016; EN 60601-1:2006+A1:2013; EN 60601-1-2:2014; EN 60601-1-6:2010; ISO 14971:2019; EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN 62366-1:2015;EN 62304:2015; EN ISO 15004-1:2009; EN ISO 15223-1:2016; EN 1041:2008;**

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

IDENTIFICATION NUMBER

**CE** 0123

(EC) CERTIFICATE(S):      No. G1 060982 0011 Rev.03



EUROPEAN REPRESENTATIVE:      **Shanghai International Holding Corp. GmbH (Europe)**  
**Eiffestrasse, 80, 20537, Hamburg, Germany**  
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START OF CE-MARKING:      2020-01-14  
PLACE, DATE OF DECLARATION:      TIANJIN,2020-01-15

SIGNATURE:

NAME: XUEQIAO WANG  
POSITION: GENERAL MANAGER