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

MANUFACTURER: TIANJIN SUOWEI ELECTRONIC TECHNOLOGY CO., LTD.

Room 2-201, 2#Building, No.6, Zhuyuan Road, Huayuan Industrial Zone, Tianjin, China

EUROPEAN REPRESENTATIVE: **Shanghai International Trading Corp. GmbH (Hamburg)**

Add: **Eiffestrasse 80, 20537 Hamburg，Germany**

PRODUCT:

1	A Scan	SW-1000	Class III
2	Pachymeter	SW-1000	Class III
3	A Scan and Pachymeter combine unit	SW-1000	Class III
4	Ophthalmic AB Scan	SW-2000	Class III
5	Ophthalmic AB Scan	SW-2100	Class III
6	Full-Scale Ultrasound Bio-Microscope	SW-3200S	Class III
7	Corneal Topographer	SW-6000	Class II
8	Keratometer	SW-100	Class II
9	Re-Bound Tonomter	SW-500	Class II

CONFORMITY ASSESSMENT ROUTE: Annex II .3

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: IEC 60601-1: 2005;IEC 60601-1-2:2007 (Third Edition)
IEC 60601-2-37:2007;EN ISO 15004-1:2006;

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

IDENTIFICATION NUMBER CE 0123

(EC) CERTIFICATE(S):

START OF CE-MARKING: TIANJIN SUOWEI ELECTRONIC TECHNOLOGY CO.,LTD.

PLACE, DATE OF ISSUE: *TIANJIN, 2011/04/25*

SIGNATURE: Xueqiao Wang

NAME

POSITION (RESPONSIBLE SENIOR EXECUTIVE)