

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, 2011/04/23**

SIGNATURE:

Xueqiao Wang

NAME

POSITION (RESPONSIBLE SENIOR EXECUTIVE)