

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: VISION SCREENER *TYPE: SW-800* *UMDNS CODES: 12811*

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

CONFORMITY ASSESSMENT ROUTE: *ANNEX II.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+A1:2013; EN 60601-1-2:2007; EN 60601-1-6:2010; EN ISO 14971:2012; 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

CE 0123

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



EUROPEAN REPRESENTATIVE: *Shanghai International Holding Corp. GmbH (Europe)*

START OF CE-MARKING:

PLACE, DATE OF DECLARATION: *TIANJIN, 2020-01-14*

SIGNATURE:

NAME: XUEQIAO WANG
POSITION: GENERAL MANAGER