

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 2017/745 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: Ophthalmic A Scan

TYPE: SW-1000 , SW-1000 P, SW-1000 A/P **UMDNS CODES:** 11389

CLASSIFICATION - ANNEX IX: IIa

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 2017/745 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; IEC 60601-2-37:2007; ISO 14971:2019; EN ISO 10993-1:2009; EN ISO 10993-5:2009; ISO 10993-10:2010; EN 62366-1:2015; EN 62304:2015; EN ISO 15004-1:2009; EN ISO 15223-1:2016; EN 1041:2008; IEC 61157:2007.

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

EC REP

EUROPEAN REPRESENTATIVE:

Shanghai International Holding Corp. GmbH (Europe)
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START OF CE-MARKING:

2011-04-14

PLACE, DATE OF DECLARATION:

TIANJIN, 2020-01-15

SIGNATURE:

NAME: XUEQIAO WANG

POSITION: GENERAL MANAGER