

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

MANUFACTURER: Edan Instruments, Inc.
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District, Pingshan District, 518122 Shenzhen, P.R.China

EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH
Eiffestrasse 80 20537 Hamburg Germany

PRODUCT/MODEL: **Diagnostic Ultrasound System/ Acclarix AX3, Acclarix AX3 Exp, Acclarix AX3 Super, Acclarix AX25, Acclarix AX28, Acclarix AX2, Acclarix AX2 Exp, Acclarix AX2 Super, Acclarix AX15, Acclarix AX18**
The accessories(see Annex 1) are used together with the product

GMDN [NAME/CODE]: General ultrasound imaging system, line-powered /40761

CLASSIFICATION: Class II a, Rule 10 According To Annex IX of the MDD

CONFORMITY ASSESSMENT ROUTE: Annex II excluding (4).

WE, EDAN INSTRUMENTS, INC., HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 INCLUDING AMENDMENTS BY DIRECTIVE 2007/47/EC.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: EN 60601-1:2006+A1:2013, EN 60601-1-2:2015, EN 62366-1:2015, EN 60601-2-37:2008+A1:2015, EN 62304: 2006+A1: 2015, EN ISO14971:2012, EN ISO10993-1:2009, EN ISO10993-5:2009, EN ISO10993-10:2013, EN ISO 15223-1:2016, EN 1041: 2008+A1: 2013, EN ISO 780:2015

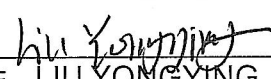
NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER 0123

(EC) CERTIFICATE(S): G1 091264 0006 REV. 01 VALID UNTIL: 2022-09-17

START OF CE-MARKING: 2019-05-30

PLACE, DATE OF ISSUE: SHENZHEN, 2019.6.11

SIGNATURE: 
NAME LIU YONGYING
MANAGEMENT REPRESENTATIVE

ANNEX 1

THE ACCESSORIES USED TOGETHER WITH THE PRODUCT 【Diagnostic Ultrasound System/Acclarix AX3, Acclarix AX3 Exp, Acclarix AX3 Super, Acclarix AX25, Acclarix AX28, Acclarix AX2, Acclarix AX2 Exp, Acclarix AX2 Super, Acclarix AX15, Acclarix AX18】 IN EC DECLARATION OF CONFORMITY

Applied Part	Part Number	Manufacturer	Class
Transducer E8-4Q	02.01.214799	EDAN	II a
Transducer L17-7Q	02.01.214800	EDAN	II a
Transducer C5-2Q	02.01.214775	EDAN	II a
Transducer L12-5Q	02.01.214797	EDAN	II a
Transducer P5-1Q	02.01.214798	EDAN	II a

SIGNATURE:

Zhang Renfu 2019.6.11
NAME: ZHANG RENFU

TITLE: PRODUCT LINE MANAGER