



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: **Ultrasonic Pocket Doppler/ SD1**
The accessories are used together with the product

GMDN [NAME/CODE]: Foetal Doppler system / 34040

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 60601-1-6: 2010+A1:2015, EN 60601-1-11: 2015, EN 60601-2-37:2008+A1:2015, EN ISO14971:2012, EN ISO10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN 62304:2006+A1:2015, EN 62366-1:2015, 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: 2017-08-18

PLACE, DATE OF ISSUE: SHENZHEN, 2019.9.9

SIGNATURE: 
NAME **LIU YONGYING**
MANAGEMENT REPRESENTATIVE