

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 (Europe)
Eiffestrasse 80 D-20537 Hamburg Germany

PRODUCT/MODEL: **Ultrasonic Pocket Doppler/ SONOTRAX Lite,
SONOTRAX Basic,
SONOTRAX Basic A,
SONOTRAX Pro,
SONOTRAX II,
SONOTRAX II Pro,
SONOTRAX Vascular**

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 DERECTIVE 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: 2007, EN 60601-2-
37:2008, EN ISO14971:2012, EN ISO10993-1:2009, EN ISO 10993-5:2009, EN ISO
10993-10:2010, EN 62304:2006, EN 62366:2008, EN 980: 2008, EN 1041: 2008**

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

IDENTIFICATION NUMBER

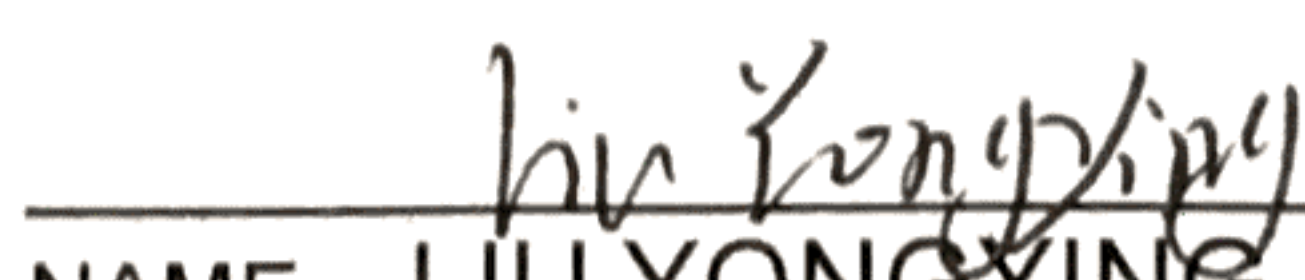


(EC) CERTIFICATE(S): G1 17 05 91264 006 VALID UNTIL: 2022-09-17

START OF CE-MARKING: 2002-09-25

PLACE, DATE OF ISSUE: SHENZHEN, 2017.9.8

SIGNATURE:


NAME LIU YONGYING
MANAGEMENT REPRESENTATIVE