

DECLARATION OF CONFORMITY TO Regulation(EU) 2017/745 CONCERNING MEDICAL DEVICES

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

SRN: CN-MF-000009957

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

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

ACCESSORIES: Refer to Annex 1

EMDN [NAME/CODE]: FOETAL HEARTBEAT DETECTORS / Z12080103

Basic UDI-DI: 69444138SonotraxSC8

Classification: Class IIa, Rule 10 According To Annex VIII of the MDR

CONFORMITY ASSESSMENT ROUTE: ANNEX IX EXCLUDING CHAPTER II.

WE, EDAN INSTRUMENTS, INC., HERE WITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE PROVISIONS OF REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON MEDICAL DEVICE.

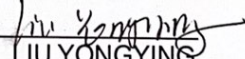
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE MANUFACTURER

STANDARDS APPLIED: EN 60601-1:2006+A1:2013, EN 60601-1-2: 2015, EN 60601-2-37:2015, EN 61266: 1995, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN 62304:2006+A1:2015, EN 62366-1:2015, EN 1041: 2008+A1:2013, EN ISO 780:2015, EN ISO 10993-1:2020, EN ISO 14971:2019, EN ISO 15223-1:2021

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

IDENTIFICATION NUMBER 0123
(EC) CERTIFICATE(S): G10 091264 0025 Rev. 01 VALID UNTIL: 2026-02-17

START OF CE-MARKING: 2002-09-25
PLACE, DATE OF ISSUE: SHENZHEN, 2023.3.10

SIGNATURE: 
NAME **LIU YONGYING**
MANAGEMENT REPRESENTATIVE



ANNEX 1

THE ACCESSORIES ARE USED TOGETHER WITH THE PRODUCT [SONOTRAX LITE, SONOTRAX BASIC, SONOTRAX PRO, SONOTRAX BASIC A, SONOTRAX II, SONOTRAX II PRO] IN EC DECLARATION OF CONFORMITY.

Product Name	Model/Type Reference	Manufacturer	Classification
Ultrasonic Probe	2.0 MHz Obstetrical Probe	EDAN	Ila
	3.0 MHz Obstetrical Probe	EDAN	Ila
	4.0 MHz Vascular Probe	EDAN	Ila
	5.0 MHz Vascular Probe	EDAN	Ila
	8.0 MHz Vascular Probe	EDAN	Ila