

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

MANUFACTURER: Edan Instruments, Inc.
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Pingshan District, 518122 Shenzhen, P.R.China
SRN: CN-MF-000009957

EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg Germany
SRN: DE-AR-000000001

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

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 CHAPTERS I AND III.

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 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-
10:2023, EN ISO 10993-23:2021, EN 62304:2006+A1:2015, IEC 62366-1: 2015+ A1:
2020, IEC 60601-1-6: 2010+ A1: 2013+ A2: 2020, EN 1041: 2008+A1:2013, EN ISO
780:2015, 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. 03 VALID UNTIL: 2026-02-17

START OF CE-MARKING: 2002-09-25
PLACE, DATE OF ISSUE: SHENZHEN, 2020.10.16

SIGNATURE:


NAME **LIU YONGYING**
MANAGEMENT REPRESENTATIVE

ANNEX 1

Accessories List:

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	Class
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

INDICATIONS FOR USE:

The SONOTRAX Series Ultrasonic Pocket Dopplers (hereinafter called "the Doppler") are intended to be used by health care professionals including registered nurses, practical nurses, midwives, ultrasound technicians, and physician assistants, by prescription from licensed physicians in hospitals, clinics and private offices.

The 2 MHz and/or 3 MHz waterproof probes are indicated for the detection of fetal heart rate from early gestation thru delivery and as a general indication of fetal well being. They can also be used to verify fetal heart viability.

The 4 MHz, 5 MHz and/or 8 MHz waterproof vascular probes are indicated for the detection of blood flow in veins and arteries for assisting in the detection of peripheral vascular disease.

SIGNATURE:


NAME: CHENDEWEI

TITLE: PRODUCT LINE MANAGER