

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
Eiffestrasse 80 20537 Hamburg Germany

PRODUCT/MODEL: Ultrasonic Pocket Doppler/SONOTRAX Lite,
SONOTRAX Basic, SONOTRAX Pro, SONOTRAX Basic
A, SONOTRAX II, SONOTRAX II Pro
The accessories are used together with the product

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.

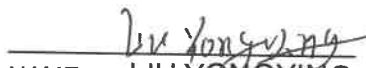
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE
MANUFACTURER

STANDARDS APPLIED: EN 60601-1:2006+A1:2013, EN 60601-1-2: 2015, EN 60601-2-
37:2015, EN 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): G10 091264 0025 REV. 01 VALID UNTIL: 2026-02-17

START OF CE-MARKING: 2002-09-25
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SIGNATURE: 
NAME LIU YONGYING
MANAGEMENT REPRESENTATIVE