EDAN INSTRUMENTS, INC.

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

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
PLACE, DATE OF ISSUE:	SHENZHEN, 2022.P.10
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