

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: **Fetal Telemetry System/ FTS-3**
The accessories are used together with the product(refer to the ANNEX 1)

EMDN [NAME/CODE]: VITAL SIGNS MONITORING INSTRUMENTS / Z120302

Basic UDI-DI: 69444138FTS3UT

CLASSIFICATION: Class **IIb**, 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.

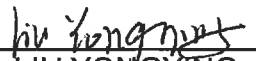
EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE MANUFACTURER

STANDARDS APPLIED: EN 60601-1:2006+A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010+A1: 2015, EN 60601-1-8:2007+A1:2013, EN 60601-2-27: 2014, EN 60601-2-37:2008+A1: 2015, EN IEC 80601-2-49: 2019, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 14155:2011, 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: 2022-05-31
PLACE, DATE OF ISSUE: SHENZHEN, 2023. 11. 10 .

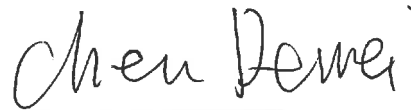
SIGNATURE: 
NAME **LIU YONGYING**
MANAGEMENT REPRESENTATIVE

ANNEX 1

THE ACCESSORIES OF THE PRODUCT FTS-3 IN EC DECLARATION OF CONFORMITY

No.	Part Number	Description	Manufacturer	Class
1	02.01.217510	Wireless Ultrasound Transducer (European Standard)	EDAN	Ila
2	02.01.217511	TOCO-T Wireless TOCO Transducer (European Standard)	EDAN	Ila
3	02.01.217514	Wireless TOCO-E Transducer	EDAN	Ila

SIGNATURE:



NAME: CHENDEWEI

TITLE: PRODUCT LINE MANAGER