

## 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 (Europe)  
Eiffestrasse 80, 20537 Hamburg, Germany  
SRN: DE-AR-000000001

**PRODUCT/MODEL:** Biofeedback and Stimulation System/ PA4 Pro, PA4 Plus, PA4, PA36, PA38, PA35, PA39, PA40

**EMDN [NAME/CODE]:** PELVIC FLOOR REHABILITATION DEVICES – OTHER/  
U070399

**Basic UDI-DI:** 69444138PAS4B

**CLASSIFICATION:** Class IIa, Rule 9 According To Annex VIII of the MDR

**CONFORMITY ASSESSMENT ROUTE:** ANNEX IX CHAPTER I.

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+A2:2021, EN 60601-1-2:2015+A1:2021, EN 60601-1-6:2010+A2:2021, EN 60601-2-10: 2015+ A1: 2016, EN 60601-2-40:2019, 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, EN 62366-1:2015+A1:2020, EN ISO 20417: 2021, 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 (EU) CERTIFICATE(S):** 0123  
G15 091264 0085 REV.00      VALID UNTIL: 2031-02-17

**START OF CE-MARKING:** 2022-06-20  
**PLACE, DATE OF ISSUE:** SHENZHEN, 2026.2.20

**SIGNATURE:**   
NAME LIU YONGYING  
MANAGEMENT REPRESENTATIVE

## 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 (Europe)  
Eiffestrasse 80, 20537 Hamburg, Germany  
SRN: DE-AR-000000001

**PRODUCT/MODEL:** Biofeedback and Stimulation System/ PR8,PR4 Pro, PR40 Pro, PR36 Pro, PR4, PR40, PR36, PR35, PR38, PR39

**EMDN [NAME/CODE]:** PELVIC FLOOR REHABILITATION DEVICES – OTHER/ U070399

**Basic UDI-DI:** 69444138PRS5W

**CLASSIFICATION:** Class IIa, Rule 9 According To Annex VIII of the MDR

**CONFORMITY ASSESSMENT ROUTE:** ANNEX IX CHAPTER I.

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

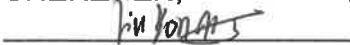
**STANDARDS APPLIED:** EN 60601-1:2006+A2:2021, EN 60601-1-2:2015+A1:2021, EN 60601-1-6:2010+A2:2021, EN 60601-2-10: 2015+ A1: 2016, EN 60601-2-40:2019, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 10993-23: 2021, EN 62304:2006+A1:2015, EN 62366-1:2015+A1:2020, EN ISO 20417: 2021, 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 (EU) CERTIFICATE(S):** 0123  
G15 091264 0085 REV.00      VALID UNTIL: 2031-02-17

**START OF CE-MARKING:** 2022-06-20

**PLACE, DATE OF ISSUE:** SHENZHEN, 2026.2.24

**SIGNATURE:**   
NAME LIU YONGYING  
MANAGEMENT REPRESENTATIVE



**ANNEX 1: Accessory list**

<b>Product name</b>	<b>Model/Type Reference</b>	<b>Manufacturer</b>	<b>Classification</b>
Pressure Probe	PV	EDAN	IIa

SIGNATURE/ DATE:

*Zhang Hong 2016.2.24*

NAME: ZHANG HONG

TITLE: PRODUCT LINE MANAGER