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 (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	0123
(EU) CERTIFICATE(S):	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:	Liu Yongying NAME LIU YONGYING MANAGEMENT REPRESENTATIVE

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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
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PLACE, DATE OF ISSUE:	SHENZHEN, 2026.2.24
SIGNATURE:	Liu Yongying NAME LIU YONGYING MANAGEMENT REPRESENTATIVE

ANNEX 1: Accessory list

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

SIGNATURE/ DATE: Zhang Hong 2016.2.24

NAME: ZHANG HONG

TITLE: PRODUCT LINE MANAGER