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:	**Ultrasonic Transducer/ (Model refer to the ANNEX 1)**
EMDN [NAME/CODE]:	ULTRASOUND PROBES / Z110402
Basic UDI-DI:	6944138UTOBC9
CLASSIFICATION:	Class IIa , Rule 10 According To Annex VIII OF the MDR
CONFORMITY ASSESSMENT ROUTE:	ANNEX IX .

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 62366-1:2015 +A1:2020, EN 60601-1-6:2010+A2:2021，EN 60601-2-37:2008+A1:2015, EN 61266: 1995, 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 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:	2026.9.23
PLACE, DATE OF ISSUE:	SHENZHEN, 2026.9.23
SIGNATURE:	NAME LIU YONGYING MANAGEMENT REPRESENTATIVE

ANNEX 1

THE MODEL OF THE PRODUCT ULTRASONIC TRANSDUCER IN EC DECLARATION OF CONFORMITY

Model	Manufacturer	Classification
SONOTRAX-2MHz	EDAN	II a
SONOTRAX-3MHz	EDAN	II a
SONOTRAX-4MHz	EDAN	II a
SONOTRAX-5MHz	EDAN	II a
SONOTRAX-8MHz	EDAN	II a
SD3-2MHz	EDAN	II a
SD3-3MHz	EDAN	II a
SD3-4MHz	EDAN	II a
SD3-5MHz	EDAN	II a
SD3-8MHz	EDAN	II a
SD5-2MHz	EDAN	II a
SD5-3MHz	EDAN	II a
SD6-2MHz	EDAN	II a
SD6-3MHz	EDAN	II a
US-SF	EDAN	II a
US-TF	EDAN	II a
US-SAF	EDAN	II a
US-TAF	EDAN	II a
US-T	EDAN	II a
WT6-US	EDAN	II a
BT6-US	EDAN	II a
MS3-109301(D)	EDAN	II a
MS3-109301(C)	EDAN	II a
MS3-109301(B)	EDAN	II a