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:	**PC ECG / SE-1515**
EMDN [NAME/CODE]:	ELECTROCARDIOGRAPHS / Z120503
Basic UDI-DI:	69444138SE1515SGK
CLASSIFICATION:	Class II a, Rule 10 According To Annex VIII OF the MDR
CONFORMITY ASSESSMENT ROUTE:	ANNEX IX CHAPTERS I AND III

INTENDED USE: SE-1515 PC ECG is intended to acquire, process and store ECG signals from adult and pediatric patients undergoing stress exercise test or resting test. The SE-1515 PC ECG is intended to be used only in hospitals and healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the SE-1515 PC ECG can help users to analyze and diagnose heart diseases. However, the ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only

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 60601-2-25:2015, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 10993-23: 2021,EN ISO 14971:2019, EN 62304:2006+A1:2015, EN 62366-1:2015+A1:2020, EN ISO 15223-1:2021, EN ISO 20417:2021 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. 03 VALID UNTIL: 2026-02-17
START OF CE-MARKING:	2014-03-04
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SIGNATURE:	Liu Yongying NAME LIU YONGYING MANAGEMENT REPRESENTATIVE