

**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 IIa, Rule 10 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 60601-2-25:2015, 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 82304-1: 2017, 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

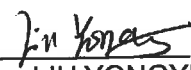
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SIGNATURE:


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MANAGEMENT REPRESENTATIVE