



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
Eiffestrasse 80 20537 Hamburg Germany

PRODUCT/MODEL: **Holter System / SE-2003,SE-2012**

EMDN [NAME/CODE]: ECG HOLTER RECORDERS / Z12050403

Basic UDI-DI: 69444138SE2003SFG

CLASSIFICATION: Class II a, Rule 10 According To Annex VIII of the MDR

CONFORMITY ASSESSMENT ROUTE: ANNEX IX EXCLUDING CHAPTER II.

WE, EDAN INSTRUMENTS, INC., HEREBY 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+A1:2013, EN 60601-1-2:2015, EN 60601-1-6: 2010+A1:2015, EN 60601-2-47:2015, EN 60601-1-11:2015, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 14971:2019, EN 62304:2006+A1:2015, EN 62366-1:2015, EN ISO 15223-1:2021, EN 1041:2008+A1:2013, EN ISO 780:2015**

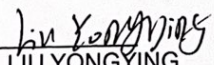
NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER 0123

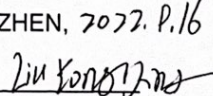
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SIGNATURE: 
NAME LIU YONGYING
MANAGEMENT REPRESENTATIVE

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IDENTIFICATION NUMBER	0123
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