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:	**Electrocardiograph/ SE-601A, SE-601B, SE-601C**
EMDN [NAME/CODE]:	ELECTROCARDIOGRAPHS / Z120503
Basic UDI-DI:	69444138SE601SKC
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., HERE WITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE 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 60601-2-25:2015,** 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
(EC) CERTIFICATE(S):	G10 091264 0025 REV. 01 VALID UNTIL: 2026-2-17
START OF CE-MARKING:	2008-11-20
PLACE, DATE OF ISSUE:	SHENZHEN, 2022.9.16
SIGNATURE:	NAME LIU YONGYING MANAGEMENT REPRESENTATIVE

Digitally signed by Cobzari-Turcan Rodica
Date: 2023.07.01 14:20:30 EEST
Reason: MoldSign Signature
Location: Moldova