

**DECLARATION OF CONFORMITY TO
Regulation(EU) 2017/746
CONCERNING IN VITRO DIAGNOSTIC 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
SRN: DE-AR-000000001

PRODUCT/MODEL: Blood Gas and Chemistry Analyzer/ i15, i15A

EMDN [NAME/CODE]: BLOOD GAS ANALYSERS / W02010401

Basic UDI-DI: 69444138i15SVA

CLASSIFICATION: Class A, Rule 5b) According To Annex VIII of the IVDR

CONFORMITY ASSESSMENT ROUTE: ANNEX IX

WE, EDAN INSTRUMENTS, INC., HERE WITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE THE PROVISIONS OF REGULATION (EU) 2017/746 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 ISO 14971: 2019, IEC 61010-1: 2017, IEC 61010-2-101: 2018, EN 61326-1:2013, EN 61326-2-6:2020, EN 62366-1: 2015, EN 62304: 2006+A1: 2015, EN 13612:2002, ISO 20916:2019, EN ISO 18113-1:2011, EN ISO 18113-3: 2011, EN ISO 15223-1: 2021, IEC/TR 60878:2015, EP05-A3, EP06-A, EP07-A3/EP37, EP09C 3RD EDITION: 2018, EP17-A2, EP28-A3C

CE MARK



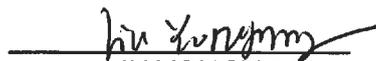
START OF CE-MARKING:

2013-7-10

PLACE, DATE OF ISSUE:

SHENZHEN, 2023.7.14

SIGNATURE:



NAME LIU YONGYING
MANAGEMENT REPRESENTATIVE