

**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 (Europe)
Eiffestrasse 80 20537 Hamburg Germany
SRN: DE-AR-000000001

PRODUCT/MODEL: Blood Gas and Chemistry Controls /QC Level 1, QC Level 2,
QC Level 3

EMDN [NAME/CODE]: ELECTROLYTE CONTROLS/ W0101050204

Basic UDI-DI: 69444138BMControlTU

CLASSIFICATION: Class C, Rule 3(j) 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 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, EN 13612:2002, EN ISO 23640:2015, EN ISO 17511:2021, EN ISO 18113-1:2011, EN ISO 18113-2: 2011, IEC 62366:2020, EN ISO 15223-1: 2021

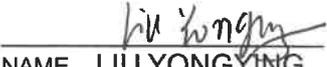
NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, 80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER 0123

EU CERTIFICATE(S): V10 091264 0062 REV. 00 VALID UNTIL: 2028-11-05
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SIGNATURE: 
NAME LIU YONGYING
MANAGEMENT REPRESENTATIVE