

**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

EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH
Eiffestrasse 80 20537 Hamburg Germany

PRODUCT/MODEL: Blood Gas and Chemistry Calibrant Fluid Pack /CP50, CP100

EMDN [NAME/CODE]: CALIBRATORS MULTICOMPONENT (CC) / W0101050301

Basic UDI-DI: 69444138BGCFPND

SRN: CN-MF-000009957

CLASSIFICATION: Class C, Implementation Rule 1.5 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, ISO 17511:2020, ISO 18113-1:2022, ISO 18113-2: 2022, EN ISO 15223-1: 2021

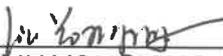
NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, 80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER 0123

EU CERTIFICATE(S): V10 091264 0062 REV. 00 VALID UNTIL: 2028-11-05
V74 091264 0055 REV. 00 VALID UNTIL: 2028-11-06

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SIGNATURE: 
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MANAGEMENT REPRESENTATIVE