

**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 Test Cartridge / MicroSample-BG10

EMDN [NAME/CODE]: ELECTRODES OR CASSETTES FOR BLOOD GAS ANALYSIS
INCL. ELECTROLYTES / METABOLITES - POC / W01010606

Basic UDI-DI: 69444138MicrosampleBG103K

SRN: CN-MF-000009957

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 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, ISO 20916:2019, EN ISO 23640:2015, EN 13641:2002, ISO 18113-1:2022, ISO 18113-2:2022, EN ISO 15223-1: 2021, EP05-A3, EP06-A, EP07-A3, EP37, EP09C 3RD EDITION:2018, EP17-A2, EP28-A3C, IEC/TR 60878:2015

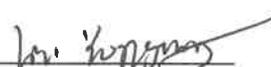
NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, 80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER 0123

EU CERTIFICATE(S): V10 091264 0062 REV. 00 VALID UNTIL: 2028-11-05
V74 091264 0045 REV. 00 VALID UNTIL: 2028-11-06

START OF CE-MARKING: 2013-07-10

PLACE, DATE OF ISSUE: SHENZHEN 2026.1.18

SIGNATURE: 
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MANAGEMENT REPRESENTATIVE