



## EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class D Devices, Class C and B Devices for self-/near-patient testing, Class C Devices Companion Diagnostics)

**No. V10 091264 0062 Rev. 00**

### Manufacturer:

**Edan Instruments, Inc.**

#15 Jinhui Road, Jinsha Community, Kengzi Sub-District  
Pingshan District  
518122 Shenzhen  
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000009957

### Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)  
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s). The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to the applicable Section(s) of Annex IX Chapter II is necessary in addition to this EU Quality Management System Certificate.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:V10\\_091264\\_0062\\_Rev\\_00](http://www.tuvsud.com/ps-cert?q=cert:V10_091264_0062_Rev_00)

**Report No.:** BJ21089108

**Valid from:** 2023-11-06

**Valid until:** 2028-11-05

Marta Carnielli  
Head of Certification IVD

**Issue date:** 2023-11-06



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**Classification:** Class B  
**Device Group:** W01010606 - ELECTRODES OR CASSETTES FOR BLOOD GAS ANALYSIS INCL. ELECTROLYTES / METABOLITES - POC  
**Intended Purpose:** IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

**Classification:** Class C  
**Device Group:** W01010606 - ELECTRODES OR CASSETTES FOR BLOOD GAS ANALYSIS INCL. ELECTROLYTES / METABOLITES - POC  
**Intended Purpose:** IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

**Classification:** Class C  
**Device Group:** W0101050204 - ELECTROLYTE CONTROLS  
**Intended Purpose:** IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

**Classification:** Class C  
**Device Group:** W0101050301 - CALIBRATORS MULTICOMPONENT (CC)  
**Intended Purpose:** IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

**The validity of this certificate depends on conditions and/or is limited to the following:** -none-

### Revision History:

| Rev. | Dated      | Report     | Description      |
|------|------------|------------|------------------|
| 00   | 2023-11-06 | BJ21089108 | Initial issuance |