ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

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

Report No.: BJ21089108

Valid from: 2023-11-06

Valid until: 2028-11-05

Digitally signed by Bolea Petru
Date: 2026.01.19 16:47:06 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Marta Carnielli
Head of Certification IVD

Issue date: 2023-11-06

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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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

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