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-MDR-099

Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 091264 0085 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 quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective aspects relating to
- establishing, securing, and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class III or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G15 091264 0085 Rev. 00

Report No.: BJ25089107
Preceding Certificate No.: G10 091264 0025 Rev. 03

Valid from: 2026-02-18
Valid until: 2031-02-17

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-12-19

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Classification:	Class IIa
Device Group:	MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters
Classification:	Class IIa
Device Group:	MDA 0305 - Active non-implantable devices for stimulation or inhibition
Classification:	Class IIa
Device Group:	MDA 0202 - Active non-implantable imaging devices utilising non-ionizing radiation
Classification:	Class IIa
Device Group:	MDA 0315 - Software
Classification:	Class IIa
Device Group:	MDA 0204 - Other active non-implantable devices for monitoring and/or diagnosis
Classification:	Class IIa
Device Group:	MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
Classification:	Class IIb
Device Group:	V030102 - BODY TEMPERATURE MONITORING PROBES
Intended Purpose:	The temperature probes are intended to be used for body temperature measurement, which are applied to the skin, oral or to the rectum.
Classification:	Class IIb
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	The product is intended for monitoring, displaying and transferring of multiple physiological parameters for fetus and pregnant women.
Classification:	Class IIb
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Intended Purpose:	The product is intended for monitoring, displaying and transferring of multiple physiological parameters.
Classification:	Class IIb
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	The product is intended for monitoring, displaying, reviewing, storing, alarming, and transferring of multiple physiological parameters.
Classification:	Class IIb
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	The product is intended for measuring SpO2 and pulse rate connecting to devices with blood oxygen measurement function.

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Certificate No. G15 091264 0085 Rev. 00

Classification:	Class IIb
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	The product is intended for monitoring, displaying, reviewing, storing, alarming, and transferring of multiple physiological parameters for fetus and pregnant women.
Classification:	Class IIb
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	The product is a software intending for monitoring, displaying, reviewing, storing, alarming, and transferring of multiple physiological parameters.
Classification:	Class IIb
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	The product is intended for monitoring, displaying, reviewing, storing, alarming, and transferring of multiple physiological parameters connecting to Central Monitoring System.
Classification:	Class IIb
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	The product is intended for measuring SpO2 and pulse rate.
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2026-02-18	BJ25089107	Renewal of certificate Administrative merge / transfer to new Certificate Type

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