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 (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 091264 0025 Rev. 01

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 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards 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 quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 091264 0025 Rev. 01

Report No.: BJ21089107

Preceding Certificate No.: G10 091264 0025 Rev. 00

Valid from: 2022-05-31
Valid until: 2026-02-17
Date of Initial Issuance: 2021-02-18

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-05-31

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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No. G10 091264 0025 Rev. 01

Classification:	IIa
Device Group:	Z12050403 - ECG HOLTER RECORDERS
Intended Purpose:	-

Classification:	IIa
Device Group:	Z12050404 - BLOOD PRESSURE HOLTER RECORDERS
Intended Purpose:	-

Classification:	IIa
Device Group:	U070399 - PELVIC FLOOR REHABILITATION DEVICES - OTHER
Intended Purpose:	-

Classification:	IIa
Device Group:	Z110401 - ULTRASOUND SCANNERS
Intended Purpose:	-

Classification:	IIa
Device Group:	Z110402 - ULTRASOUND PROBES
Intended Purpose:	-

Classification:	IIa
Device Group:	Z120503 - ELECTROCARDIOGRAPHS
Intended Purpose:	-

Classification:	IIa
Device Group:	Z12080103 - FOETAL HEARTBEAT DETECTORS
Intended Purpose:	-

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No. G10 091264 0025 Rev. 01

Classification:	IIa
Device Group:	Z12080101 - FOETAL MONITORS
Intended Purpose:	-

Classification:	IIa
Device Group:	Z1203020408 - PULSE OXIMETERS
Intended Purpose:	-

Classification:	IIa
Device Group:	V03010299 - BODY TEMPERATURE MONITORING PROBES - OTHER
Intended Purpose:	-

Classification:	IIa
Device Group:	Z120801 - PRENATAL DIAGNOSTIC INSTRUMENTS
Intended Purpose:	-

Classification:	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:	IIb
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	The product is intended for monitoring, displaying and transferring of multiple physiological parameters.

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No. G10 091264 0025 Rev. 01

Classification:	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:	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.

Classification:	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:	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:	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.

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No. G10 091264 0025 Rev. 01

Classification:	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
00	2021-02-18	BJ20089102

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