Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat al dispozitivelor medicale
nr. ..... din .....

Solicitantul AELO GRUP SRL, cu sediul **mun. Chişinău, str. Mitropolit Petru Movilă 23/5, of.3** , tel./fax: **+373 79 80 77 33/02260 14 91**, e-mail: aelogrup@gmail.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Patient Monitor	Edan Instruments,INC	iX10
Patient Monitor	Edan Instruments,INC	iX12
Patient Monitor	Edan Instruments,INC	iX15
Patient Monitor	Edan Instruments,INC	X8
Patient Monitor	Edan Instruments,INC	X10
Patient Monitor	Edan Instruments,INC	X12

Se anexează următoarele acte:
Declarația pe propria răspundere;
Brosura,Certificat CE; ,Certificat ISO13485 ,
Scisoarea de Autorizare.

Data 20.06.2023 Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Cobzari-Țurcan Rodica
Date: 2023.06.20 12:10:26 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului şi Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: **„Aelo Grup" SRL** , cu sediul **mun. Chişinău, str.Mitropolit Petru Movila 23/5, of. 3**, declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele şi datele furnizate pentru notificarea dispozitivului medical:

Patient Monitor	Edan Instruments,INC	iX10
Patient Monitor	Edan Instruments,INC	iX12
Patient Monitor	Edan Instruments,INC	iX15
Patient Monitor	Edan Instruments,INC	X8
Patient Monitor	Edan Instruments,INC	X10
Patient Monitor	Edan Instruments,INC	X12

Sunt autentice şi corespund realităţii.

Cobzari Ţurcan Rodica
Administrator

Semnătura _____

Data 20.06.2023

Nr.	Generic name (device name)	Commercial name (brand)*	Model	Number EMDN*
1	Patient Monitor	Edan Instruments,INC	iX10	Z120302
2	Patient Monitor	Edan Instruments,INC	iX12	Z120302
3	Patient Monitor	Edan Instruments,INC	iX15	Z120302
4	Patient Monitor	Edan Instruments,INC	X8	Z120302
5	Patient Monitor	Edan Instruments,INC	X10	Z120302
6	Patient Monitor	Edan Instruments,INC	X12	Z120302

Semnat:_____

Numele, Prenumele:Cobzari Țurcan Rodica

Administrator: Aelo Grup SRL

Adresa:

str. Petru Movilă,23/5, ap.3

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "AELO GRUP" IDNO REPUBLICA MOLDOVA

№: 2023/IM013UZ

Date: 24/3,2023

CONFIRMATION LETTER

We, **Edan Instruments, Inc**. ,based in No.15 Jinhui Rd., Shenzhen, 518122, P.R.China, assign **AELO GRUP SRL** , based in Str Petru Movila 23/5 of 3, Chisinau MD -2004, Moldova, as **authorized representative** in correspondence with the conditions if directive 93/42/EEC, 98/79/EEC and 90/385/EEC.
We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date:24/3/2023

Signed:

EDAN INSTRUMENTS, INC.
15 Jinhui Road, Pingshan District, Shenzhen 518122, P.R. China
T +86-755-26898326 | F +86.755.26898330 | www.edan.com

EDAN INSTRUMENTS, INC.

DECLARATION OF CONFORMITY TO REGULATION(EU) 2017/745 CONCERNING MEDICAL DEVICES

MANUFACTURER:	Edan Instruments, Inc. #15 Jinhui Road, Jinsha Community, Kengzi Sub-District, Pingshan District, 518122 Shenzhen, P.R.China
SRN:	CN-MF-000009957
EUROPEAN REPRESENTATIVE:	Shanghai International Holding Corp. GmbH Eiffestrasse 80 20537 Hamburg Germany
PRODUCT/MODEL:	**Patient Monitor / iX10, iX12, iX15**
EMDN [NAME/CODE]:	VITAL SIGNS MONITORING INSTRUMENTS/ Z120302
Basic UDI-DI:	69444138iXS9L
CLASSIFICATION:	Class **IIb**, Rule 10 According To Annex VIII OF the MDR
CONFORMITY ASSESSMENT ROUTE:	ANNEX IX EXCLUDING CHAPTER II.

WE, EDAN INSTRUMENTS, INC., HERE WITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE PROVISIONS OF REGULATION （EU）2017/745 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 60601-1: 2006+A1: 2013, EN 60601-1-2: 2015, EN 60601-1-6: 2010+A1: 2015, EN 60601-1-8: 2007+A1: 2013, EN 60601-2-25:2015, EN 60601-2-27: 2014, EN IEC 80601-2-30: 2019, EN 60601-2-34:2014, EN IEC 80601-2-49: 2019, EN ISO 80601-2-61: 2019, EN ISO 80601-2-55: 2018, EN ISO 80601-2-56: 2017+A1: 2020, EN ISO 81060-2: 2014, EN ISO 10993-1: 2020, EN ISO 10993-5: 2009, EN ISO 10993-10: 2013, EN ISO 14155: 2011, EN ISO 14971: 2019, EN 62304: 2006+A1: 2015, EN 62366-1: 2015, EN ISO 15223-1: 2021, EN 1041: 2008+A1: 2013, EN ISO 780: 2015**

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER	0123
(EC) CERTIFICATE(S):	G10 091264 0025 Rev. 01 VALID UNTIL: 2026-02-17
START OF CE-MARKING:	2022-10-31
PLACE, DATE OF ISSUE:	SHENZHEN, 2022.10.31
SIGNATURE:	Liu Yongying NAME LIU YONGYING MANAGEMENT REPRESENTATIVE

EDAN INSTRUMENTS, INC.

DECLARATION OF CONFORMITY TO REGULATION(EU) 2017/745 CONCERNING MEDICAL DEVICES

MANUFACTURER:	Edan Instruments, Inc. #15 Jinhui Road, Jinsha Community, Kengzi Sub-District, Pingshan District, 518122 Shenzhen, P.R.China
SRN:	CN-MF-000009957
EUROPEAN REPRESENTATIVE:	Shanghai International Holding Corp. GmbH Eiffestrasse 80 20537 Hamburg Germany
PRODUCT/MODEL:	**Patient Monitor / X8, X10, X12**
EMDN [NAME/CODE]:	VITAL SIGNS MONITORING INSTRUMENTS/ Z120302
Basic UDI-DI:	69444138XSGP
CLASSIFICATION:	Class **IIb**, Rule 10 According To Annex VIII OF the MDR
CONFORMITY ASSESSMENT ROUTE:	ANNEX IX EXCLUDING CHAPTER II.

WE, EDAN INSTRUMENTS, INC., HERE WITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE THE PROVISIONS OF REGULATION （EU）2017/745 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 60601-1:2006+A1:2013, EN 60601-1-2:2015, EN 60601-1-6: 2010+A1: 2015, EN 60601-1-8:2007+A1:2013, EN 60601-2-25:2015, EN 60601-2-27: 2014, EN IEC 80601-2-30: 2019, EN 60601-2-34:2014, EN IEC 80601-2-49: 2019, EN ISO 80601-2-61:2019, EN ISO 80601-2-55: 2018, EN ISO 80601-2-56: 2017+A1: 2020, EN ISO 81060-2: 2014, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10: 2013, EN ISO 14155:2011, EN ISO 14971:2019, EN 62304: 2006+A1:2015, EN 62366-1: 2015, EN ISO 15223-1: 2021, EN 1041:2008+A1:2013, EN ISO 780:2015**

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER	0123
(EC) CERTIFICATE(S):	G10 091264 0025 REV. 01 VALID UNTIL: 2026-02-17
START OF CE-MARKING:	2018-12-25
PLACE, DATE OF ISSUE:	SHENZHEN, 2022.12.12
SIGNATURE:	Liu Yongying NAME LIU YONGYING MANAGEMENT REPRESENTATIVE

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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

Issue date: 2022-05-31

Christoph Dicks
Head of Certification/Notified Body

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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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
BS-MDR-099

TÜV SÜD 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

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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TÜV SÜD 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

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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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

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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BS-MDR-099

TÜV SÜD 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

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 091264 0016 Rev. 03

Holder of Certificate: **Edan Instruments, Inc.**
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District
Pingshan District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuvsud.com/ps-cert

Scope of Certificate:

Design and Development, Production and Distribution of Transcranial Doppler System, Fetal Monitor, Fetal & Maternal Monitor, Patient Monitor, Central Monitoring System, Ultrasonic Pocket Doppler, Electrocardiograph, Pulse Oximeter, Digital Ultrasonic Diagnostic Imaging System, STRESS ECG, PC ECG, Vital Signs Monitor, Finger Oximeter, Ultrasonic TableTop Doppler, Data Management Software, Trolley (for medical use), ECG Electrode, Holter System, Treadmill (for medical use), Diagnostic Ultrasound System, Ultrasonic Imaging Management System, Blood Gas and Chemistry Analysis System (Including Blood Gas and Chemistry Analyzer, Calibrant Fluid Pack, Test Cartridge, Controls, External Electronic Simulator, Capillary Adaptor, Ampoule adaptor), Hematology Analyzer, Reagents for Hematology Analyzer (Including Diluent, Lyse, Cleaner, Bleach, Hematology Control, Hematology Calibrator), Video Colposcope, Ultrasonic Transducer, TOCO Transducer, SPO2 Sensor, Temperature Probe, ECG Cable, Telemetry Transmitter, NIBP Cuff, Specific Protein Immunoassay System (Including Protein Assay Kit, Assay Buffer, Sample Dilution Buffer, Washing Buffer, Protein Analyzer), Biofeedback and Stimulation System, EMG/ Stimulation Sensor, Ambulatory Blood Pressure Monitor, NIBP Tube, Connection Cable, Water Trap, Needle Guide Bracket, ECG Analysis Software, Fetal Telemetry System, Electrosurgical Generator.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 091264 0016 Rev. 03

Report No.:	BJ22089102
Valid from:	2022-12-01
Valid until:	2025-11-30

Date, 2022-08-18

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 091264 0016 Rev. 03

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

See Scope of Certificate

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