Digitally signed by Cobzari-Turcan Rodica
Date: 2023.06.29 10:24:24 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE
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.Chișinău, str.Mitropolit Petru Movila 23/5, ap,6,**
tel./fax: **+373 61 033 993/022 60 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:

Defibrilator Monitor Comen S5

Se anexează următoarele acte:
CE;ISO;Decalaratie de conformitate;Brosura

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	

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

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: Aelo Grup SRL,
cu sediul în: mun.Chișinău, str.Mitropolit Petru Movila 23/5, ap.6

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Defibrilator Monitor Comen S5

Sunt autentice și corespund realității.

Cobzari -Țurcan Rodica
Administrator

SOCIETATEA CU RĂSPUNDERE LIMITATĂ
S.R.L.
"AELO GRUP"
IDNO 1011
REPUBLICA MOLDOVA

Semnătura

Data 20.06.2023

EC Declaration of Conformity

Manufacturer:
Shenzhen Comen Medical Instruments Co.,Ltd.
Address:
Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R. China.

Whose Single Authorized Representative:
Lotus NL B.V.
Address:
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

SRN: NL-AR-000000121

We, the manufacturer(SRN number: CN-MF-000002236)., declare at our sole responsibility that following products

Product name	Model	Basic UDI-DI
Defibrillator Monitor	S8, S6, S5, S3	69454290DM001K6

meet the provisions of Directive 93/42/EEC

The medical device has been assigned to class IIb according to Rule 9 and Rule 10 in Annex VIII of Directive 93/42/EEC. It bears the mark

CE 1639

The product concerned has been designed and manufactured under a quality management system according to Annex II (excluding Section4) of Directive 93/42/EEC.

Compliance of the designated product with the Annex II (excluding Section4) of Directive 93/42/EEC has been assessed and certified by the Notified Body

SGS Belgium NV
SGS House Noorderlaan
87 2030 Antwerp Belgium
CertificateNo.: CN19/41057
Issuedate: 2021.03.22
Expirydate: 2028.12.31

Following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

The above mentioned declaration of conformity is exclusively under the responsibility of Shenzhen Comen Medical Instruments Co.,Ltd

Company: Shenzhen Comen Medical Instruments Co.,Ltd
Address: Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R. China.

2023.6.14
Place, date

Legally binding signature, Function

Nr.	Basic UDI-DI	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1	69454290DM001K6	**Defibrilator Monitor**	**Comen**	**S5**	**17882**

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "AELO GRUP" S.R.L. IDNO 1020009752 REPUBLICA MOLDOVA

Administrator: Cobzari Turcan Rodica

COMEN
Share With The World.

SHENZHEN COMEN MEDICAL INSTRUMENTS CO.,LTD
No.2 of FIYTA Timepiece Building, Nanhuan Avenue, Gongming
Sub-district,Guangming New District, Shenzhen, P.R.China
Web: www.comen.com E-mail: info@szcomen.com
Tel: +86-755-26408879 Fax: +86-755-26431232

We, Shenzhen Comen Medical Instruments CO., LTD, having factories at No.2 of FIYTA Timepiece Building, Nanhuan Avenue, Gongming Sub-district, Guangming New District, Shenzhen, P.R.China, assign Aelo Grup SRL, based in Petru Movila str, 23/5, of.3 Chisinau MD -2004, Republic of 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 participate in public procurements with our medical equipment, to register, notify, renew or modify the registration of our medical devices on the territory of the Republic of Moldova.

Place: Shenzhen, China Date: December 15, 2022

Signed:

COMEN MEDICAL INSTRUMENTS CO.,LTD 深圳市科曼医疗设备有限公司

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "AELO GRUP" S.R.L. IDNO 1[illegible] REPUBLICA MOLDOVA

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

TÜVRheinland®

Registration No.: HD 60150327 0001

Report No.: 17058047 008

Manufacturer: SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD.
F10-11& Sect C, F12 of BLDG 1A and
F1-5 of BLDG 2 , FIYTA Timepiece
Building, Nanhuan Avenue, Matian
Subdistrict, Guangming District
518106 Shenzhen, Guangdong
P.R. China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60144776 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-08-03

Date: 2020-08-03

Notified Body

Dipl.-Ing. W. Hsu

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1 Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60150327 0001
Report No.: 17058047 008

Manufacturer:
SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD.
F10-11& Sect C, F12 of BLDG 1A and F1-5 of BLDG 2 , FIYTA Timepiece Building, Nanhuan Avenue, Matian Subdistrict, Guangming District
518106 Shenzhen, Guangdong
P.R. China

Products:

- Anaesthetic Systems
- Syringe Pumps
- Infusion Workstation
- Infusion Pumps
- Neonatal Ventilators
- Medical Oxygen-air Blenders
- Infant Incubators
- Defibrillator/Monitors

Date: 2020-08-03

Notified Body

Dipl.-Ing. W. Hsu

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Certificate CN15/30544
The management system of

Shenzhen Comen Medical Instruments Co., Ltd.

Business Registration Address: Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, 518106, Guangdong, P.R. China
Business Operation Address: Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, 518106, Guangdong, P.R. China

Unified Social Credit Code 91440300738806174Y
has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Design, Production and Sales of Fetal& Maternal Monitor, Multi-parameter Patient Monitor, Specialized Cardiovascular Monitor, Vital Signs Monitor, Specialized Neonatal Monitor, Specialized Fetal & Maternal Monitor, Defibrillator Monitor, Central Monitoring System Software, Anaesthetic Gas Scavenging System, Infant Incubator, T-piece Infant Resuscitation System, Electrocardiograph, Infrared Ear Thermometer, Anaesthesia Machine, Infusion Pump, Infusion Workstation, Syringe Pump, Neonatal Ventilator, Medical Oxygen-air Blender, Medical Air Compressor, Ceiling Pendant, LED Surgical Light, Infant Radiant Warmer, Infant Phototherapy Equipment, Catheter-positioning Guiding System, Temperature Control System, Video Laryngoscope, Sequential Compression System, High Flow Heated Respiratory Humidifier, Emergency and Transport Ventilator, Ventilator Design and Sales of Sterile disposable laryngoscope blade

This certificate is valid from 30 April 2021 until 29 April 2024
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 7. Certified since 30 April 2015

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com
The certification information can be verified on the web site of Certification and Accreditation Administration of the People's Republic of China www.cnca.gov.cn

0005

HC SGS 9001 2015 0118

Certificate CN15/30545

The management system of

Shenzhen Comen Medical Instruments Co., Ltd.

Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 02 March 2021 until 29 April 2024
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 04 February 2024
Issue 8. Certified since 30 April 2015

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

Shenzhen Comen Medical Instruments Co., Ltd.

ISO 13485:2016
EN ISO 13485:2016

Issue 8

Detailed scope

Design, Manufacture and Distribution of
- Electrocardiograph,
- Fetal & Maternal Monitor,
- Multi-parameter Patient Monitor,
- Specialized Cardiovascular Monitor,
- Vital Signs Monitor,
- Specialized Neonatal Monitor,
- Specialized Fetal & Maternal Monitor,
- Central Monitoring System Software
- Infrared Ear thermometer
- Anaesthetic Gas Scavenging System
- LED Surgical Light
- Ceiling Pendant
- T piece Infant Resuscitation System
- Anesthesia Machine,
- Infant Radiant Warmer.
- Infant Phototherapy equipment
- Catheter-positioning guiding system (including Sterile Disposable electrode with extension wire)
- Syringe Pump
- Temperature Control System for management patient body temperature and vital physiological parameters Monitor
- Video Laryngoscope
- Sterile Disposable Laryngoscope blade
- Sequential Compression System for Prophylaxis of Vein Thrombosis and for alleviation of limb venous edema and pain
- Defibrillator Monitor
- High flow heated respiratory humidifier
- Emergency and Transport Ventilator
- Ventilator
- Operating table

UKAS MANAGEMENT SYSTEMS
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