Digitally signed by Lungu Ion
Date: 2023.06.28 13:05:58 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. **180** din **26.06.2023**

"Health Medical Solutions" SRL, cu sediul Republica Moldova, MD-2019, mun. Chișinău, str. Grenoble 128, of. 011, E-mail: info@hms.md, srl.hms.moldova@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 dispozitivelor **clasa de risc IIb, Anexa IX**:

1. **Pompă de infuzie (cu seringă)**, denumire comercială - Syringe Pump, model – **EN-S7 Smart**, producător- **Shenzhen ENMIND Technology**, țara de origine - **China**;

Se anexează următoarele acte:

1. Împuternicirea de a reprezenta **Shenzhen ENMIND Technology**, **China** din 26.05.2023;
2. Certificat CE No.HD 60144003 0001 din 02.12.2019 (valabil pînă la 27.05.2024);
3. Declarația de conformitate **Shenzhen ENMIND Technology** din 20.05.2021;
4. Certificat ISO 13485:2016 No.SX 2042744-1 din 02.09.2021 (valabil pînă la 01.09.2024);
5. Declaraţie pe proprie răspundere.

Data **26.06.2023** 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

DECLARATIE PE PROPRIE RĂSPUNDERE

"Health Medical Solutions" SRL, cu sediul Republica Moldova, MD-2019, mun. Chișinău, str. Grenoble 128, of. 011 E-mail: info@hms.md, srl.hms.moldova@gmail.com, declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

1. **Pompă de infuzie (cu seringă)**, denumire comercială - Syringe Pump, model – **EN-S7 Smart**, producător- **Shenzhen ENMIND Technology**, țara de origine - **China**;

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia *Semnătura* _____
Lungu Ion, Administrator
+37379627404, +37369423432 Data 26.06.2023

Date: 26 May 2023

LETTER OF AUTHORIZATION

To Whom it May Concern,

We, **Shenzhen ENMIND Technology Co., Ltd.**, who are official manufacturer of **syringe pump, infusion pump, infusion work station, central infusion management system, vein viewer, video laryngoscope** devices, having headquarters at **5th Floor, Block A, Defengsheng Building, No.41 Dabao Road, Bao'an District 23, Shenzhen 518101, Guangdong, P.R.China**, assign - company **HEALTH MEDICAL SOLUTIONS S.R.L.**, based at Republic of Moldova, Chișinău, MD-2019, 128, Grenoble str., OF.011.

- as authorized representative in the Republic of Moldova in correspondence with the conditions of Directive 93/42/EEC.
- We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the in territory of Republic of Moldova, and to perform Essential Duties required by Law No. 102 on 09.06.2017 regarding Medical Devices.

This Authorization letter is valid until 26 May 2025.

Signature and stamp

Anne Dong
Sales Manager
Shenzhen ENMIND Technology Co., Ltd.

EC Certificate

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

Registration No.: HD 60144003 0001

Report No.: 17055844 008

Manufacturer:
Shenzhen Enmind Technology
Co., Ltd.
Room 201, Block A
No. 1, Qianhai Road 1
Qianhaishen Port Cooperative District
Shenzhen
518000 Guangdong
China

Products:
Infusion Pumps, Syringe Pumps

(see attachment for site included)

Replaces Approval, Registration No.: DD 60109366 0001

Expiry Date: 2024-05-27

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: 2019-12-02

Date: 2019-12-02

Notified Body
TÜV Rheinland LGA Products GmbH
Fuxiu Sheng

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 60144003 0001
Report No.: 17055844 008

Manufacturer:
Shenzhen Enmind Technology Co., Ltd.
Room 201, Block A
No. 1, Qianhai Road 1
Qianhaishen Port Cooperative District
Shenzhen
518000 Guangdong
China

Site included:

5th Floor, Block A, Defengsheng Building,
No.41 Dabao Road, Bao'an District 23,
Shenzhen, 518101, P.R.China

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng

Date: 2019-12-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2042744-1

Organization: Shenzhen Enmind Technology Co., Ltd.
Room 201, Block A,
No.1, Qianhai Road 1,
Qianhaishen Port Cooperative District
Shenzhen
518000 Guangdong
P.R. China

Scope: Design and Development, Manufacture and Distribution of Infusion Pumps, Syringe Pumps and Infusion Workstations

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 10918665-100
Effective date: 2021-09-02
Expiry date: 2024-09-01
Issue date: 2021-09-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2042744-1

Organization: Shenzhen Enmind Technology Co., Ltd.
Room 201, Block A,
No.1, Qianhai Road 1,
Qianhaishen Port Cooperative District
Shenzhen
518000 Guangdong
P.R. China

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Shenzhen Enmind Technology Co., Ltd. Room 201, Block A, No.1, Qianhai Road 1, Qianhaishen Port Cooperative District Shenzhen 518000 Guangdong P.R. China	License holder
/02	c/o Shenzhen Enmind Technology Co., Ltd. 5th Floor, Block A, Defengsheng Building, No.41 Dabao Road, Bao'an District 23, Shenzhen, 518101 Guangdong P.R. China	Design and Development, Manufacture and Distribution of Infusion Pumps, Syringe Pumps and Infusion Workstations

Report No.: 10918665-100
Effective date: 2021-09-02
Expiry date: 2024-09-01
Issue date: 2021-09-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

EC Declaration of Conformity

Manufacturer:

Shenzhen Enmind Technology Co., Ltd.
Room 201,Block A,No.1,Qianhai Road 1,Qianhaishen Port Cooperative District, Shenzhen, 518000,Guangdong,China

whose single Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg， Germany

We, the manufacturer, herewith declare that the products

Infusion Pumps(EN-V7,EN-V7 Smart,EN-V5,EN-Z50,EN-V3,EN-Z30,EN-V9,EN-V9 Smart)
GMDN-Code: **13215**
BASIC-UDI-DI：**697100143001001BR**
Syringe Pumps (EN-S7,EN-S7 Smart ,EN-S3,EN-S5D,EN-S9,EN-S9Smart)
GMDN-Code: **13217**
BASIC-UDI-DI：**697100143002001BY**
Infusion Work Station(En-D7,EN-D7 Smart, En-D9,EN-D9 Smart,)
GMDN- Code: **13217**
BASIC-UDI-DI：**697100143004001CE**

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIb according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been manufactured under a quality management system according to Annex Ⅱ of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: HD 60144003 0001
Issue date: 2019-12-02
Expiry date: 2024-05-27

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

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Shenzhen Enmind Technology Co., Ltd.
Address: Room 201,Block A,No.1,Qianhai Road 1,Qianhaishen Port Cooperative District, Shenzhen, 518000,Guangdong,China
Site included： 5th Floor,Block A,Defengsheng Building,No.41 Dabao Road,Bao'an District 23,Shenzhen 518101,P.R.China

Shenzhen 2021.05.20
Place, date

Legally binding signature, Function