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

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: **Comerț-Magor S.R.L.**, cu sediul în **Moldova, mun. Chișinău MD2004, str. Bucuriei 1**, 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 dispozitivelor medicale:

Numarul de catalog	Denumire	Denumirea comerciala	Modelul	Tip Dispozitiv	Cod GMDN	Clasa de risc
50ml	Seringa perfuzor 50ml cu ac 18G	Sterile hypodermic syringes for single use	Disposable syringe 50 ml with needle 18G 1½ , 3 components, latex free, luer lock, plunger backstop, individually packed, PE bag	Sterile hypodermic syringes for single use		Clasa IIa
60ml	Seringa 60ml fara ac	Sterile hypodermic syringes for single use	Disposable syringe, 3components, latex free,catheter tip, plunger backstop, individually packed, PE bag 60 ml	Sterile hypodermic syringes for single use		Clasa IIa
150ml	Seringa 150ml fara ac	Sterile hypodermic syringes for single use	Disposable syringe, 3components, latex free,catheter tip, plunger backstop, individually packed, PE bag 150 ml	Sterile hypodermic syringes for single use		Clasa IIa

Sunt autentice și corespund realității.

Administrator Cojocaru Vladimir *Semnătura* _____

Data 17.09.2023

Digitally signed by Cojocaru Vera
Date: 2023.09.17 12:54:55 EEST
Reason: MoldSign Signature
Location: Moldova

Anexă

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. **31** din **17.09.2023**

Solicitantul **Comerț-Magor S.R.L.**, cu sediul **Moldova, mun. Chișinău MD2004, str. Bucuriei 1**, tel./fax: **022742200/022743931**, e-mail **veracojocaru@mail.ru**, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Numarul de catalog	Denumire	Denumirea comerciala	Modelul	Tip Dispozitiv	Cod GMDN	Clasa de risc
50ml	Seringa perfuzor 50ml cu ac 18G	Sterile hypodermic syringes for single use	Disposable syringe 50 ml with needle 18G 1½ , 3 components, latex free, luer lock, plunger backstop, individually packed, PE bag	Sterile hypodermic syringes for single use		Clasa IIa
60ml	Seringa 60ml fara ac	Sterile hypodermic syringes for single use	Disposable syringe, 3components, latex free,catheter tip, plunger backstop, individually packed, PE bag 60 ml	Sterile hypodermic syringes for single use		Clasa IIa
150ml	Seringa 150ml fara ac	Sterile hypodermic syringes for single use	Disposable syringe, 3components, latex free,catheter tip, plunger backstop, individually packed, PE bag 150 ml	Sterile hypodermic syringes for single use		Clasa IIa

Se anexează următoarele acte:

a) declarația de conformitate CE emisă de producător pentru dispozitivele fabricate
b) certificatul de management al calitatii pentru dispozitivele medicale ISO 13485:2016
c) actul prin care producătorul își desemnează reprezentantul

Data **17.09.2023** 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	

ANHUI HONGYU WUZHOU MEDICAL MANUFACTURER CO.,LTD.
No.2 Guanyin Road,Economic development Zone,Taihu County,Anqing,246400,Anhui PR,China.
Email:Info@hongyu-wuzhou.com;Tel:+86-0577-88671887

POWER OF ATTORNEY

The Company **Anhui Hongyu Wuzhou Medical Manufacturer Co.,ltd.**, located at No.2 Guanyin Road,economic development Zone,Taihu County,246400 Anqing,Anhui PR,China hereinafter called - «The Manufacturer», duly represented by the CEO, **Zhang Hongyu**, acting under and by virtue of the Articles of Association.

By this power of attorney authorizes:

The Company **ELECTEH S.R.L.,** Registration number: located at str.Bucuriei 1,Chisinau,MD-2004,Moldova, hereinafter called - «An authorized representative of the manufacturer».

-To represent the interests of The Manufacturer on the circulation of medical devices produced by **Anhui Hongyu Wuzhou Medical Manufacturer Co.,ltd.** on the territory of the Republic of Moldova.

- To register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.;

- To conduct negotiations;

- To sign the statements, applications, contracts and other necessary documents, including financial, with the purpose of state registration and conformity assessment of medical devices;

- To provide with technical, operational and other documentation and materials required for the state registration and conformity assessment of the medical device, to give clarifying explanation;

- To initiate changes to the registration certificate for medical devices, if it is necessary;

- To provide with other necessary information and documents for the state registration and conformity assessment of medical device;

- To make payments for the services;

- To perform other necessary actions related to the registration or conformity assessment of the medical device;

- To get the Registration certificate issued in the name of **Anhui Hongyu Wuzhou Medical Manufacturer Co.,ltd.**

This power of attorney is granted for **5 years**, with a right of substitution.

CEO **Anhui Hongyu Wuzhou Medical Manufacturer Co.,ltd.** Date Sep. 7. 2023

ANHUI HONGYU WUZHOU MEDICAL MANUFACTURER CO., LTD.
安徽宏宇五洲医疗器械股份有限公司

张洪瑜

Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 081232 0010 Rev. 02

Manufacturer:

AnHui Hongyu Wuzhou Medical Manufacturer Co.,Ltd.
No.2 Guanyin Road
Economic Development Zone
Taihu County
246400 Anqing, Anhui
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Sterile Hypodermic Syringes for Single Use, Sterile Hypodermic Needles for Single Use, Sterile Insulin Syringes for Single Use, Insulin Pen-injectors for Medical Use, Transfusion Sets for Single Use, Infusion Sets for Single Use(Gravity Feed), Burette-type Infusion Sets for Single Use, Intravenous Needles for Single Use, Blood Collection Needles for Single Use, Sterile Dental Injection Needles for Single Use, Disposable Precision Flow Regulator, Insulin Pen Needles for Single Use, Blood Collection Sets for Single Use, Sterile Safety Hypodermic Needles for Single Use, Safety Blood Collection Sets for Single Use, Safety Blood Collection Needles for Single Use

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH19735EXT01

Valid from: 2020-03-03
Valid until: 2024-05-26

Date, 2020-03-03

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

安徽宏宇五洲医疗器械股份有限公司
Anhui Hongyu Wuzhou Medical Manufacturer Co.,Ltd
Add:No.2 Guanyin Road ,Economic Development Zone,Taihu County 246400,Anqing,Anhui,PEOPLE'S REPUBLIC OF CHINA

Declaration of Conformity

Manufacturer: Anhui Hongyu Wuzhou Medical Manufacturer Co.,Ltd
Address:No.2 Guanyin Road ,Economic Development Zone,Taihu County 246400,Anqing,Anhui,PEOPLE'S REPUBLIC OF CHINA
Tel::0556-4248888; **Fax**:0556-4249999;**Post**:246400

AUTHORIZED EUROPEAN REPRESENTATIVE
Name:Shanghai International Holding Corp. GmbH (Europe)
Address:Eiffestrasse 80, 20537 Hamburg,Germany
Tel:0049-40-2513175;**Fax**:0049-40-255726

Medical Device:
-**Name of Products**: Sterile hypodermic syringes for single use ; Sterile hypodermic needles for single use ; Sterile insulin syringes for single use ; Insulin pen-injectors for medical use ; Transfusion sets for single use ; Infusion sets for single use(gravity feed) ; Burette-type infusion sets for single use ; Intravenous needles for single use ; Blood collection needles for single use ; Sterile dental injection needles for single use; Disposable precision flow regulator; insulin pen needle for single use; Blood collection set for single use; Sterile safety hypodermic needle for single use; Safety blood collection set for single use; Safety blood collection needle for single use.
-Classification: IIa

Conformity evaluation
My company production of Sterile syringes for single use with needles; Sterile hypodermic needles for single use; Sterile insulin syringes for single use; Insulin pen-injectors for medical use; Transfusion sets for single use ; Infusion sets for single use(gravity feed); Burette-type infusion sets for single use; Intravenous needles for single use; Blood collection needles for single use; Sterile dental injection needles for single use; Disposable precision flow regulator; insulin pen needle for single use; Blood collection set for single use; Sterile safety hypodermic needle for single use; Safety blood collection set for single use; Safety blood collection needle for single use, which belongs to a product IIa, According to the 93/42/EEC declaration of conformity procedure to select the authentication way , additional CE mark.

General applicable directives: COUNCIL DIRECTIVE (MDD93/42/EEC).

Notified Body: TÜV SÜD Product Service GmbH 0123

安徽宏宇五洲医疗器械股份有限公司
Anhui Hongyu Wuzhou Medical Manufacturer Co.,Ltd
Add:No.2 Guanyin Road ,Economic Development Zone,Taihu County 246400,Anqing,Anhui,PEOPLE'S REPUBLIC OF CHINA

EC Certificate(s):

NO. G2 081232 0010 Rev.02

Issue date: 2020-03-03

ANHUI HONGYU WUZHOU MEDICAL MANUFACTURER CO., LTD.
安徽宏宇五洲医疗器械股份有限公司

Address: No.2 Guanyin Road ,Economic Development Zone,Taihu County 246400,Anqing,Anhui,PEOPLE'S REPUBLIC OF CHINA

General Manager: ZHANG HONGYU

Date: 18th, JAN, 2023

张洪瑜