PROCURĂ

16. 10 .2023. Chisinau
(localitatea)

Prin prezenta procură **"COMERŢ-MAGOR" S.R.L.** .
(denumirea persoanei juridice)
IDNO : **1003600022518** , reprezentată legal prin

Administrator **Vladimir Cojocaru** , IDNP **0970403542457** ,

seria/numărul buletinului de identitate **A48142861** , eliberat la **06.11.2007** ,
activând în baza **Statutului**,

împuterniceşte compania **„ELECTEH" S.R.L.**,
IDNO: **1003600113045**, reprezentată legal prin

Administrator **Vera Cojocaru,** IDNP **0981605484988** , seria/numărul buletinului **A48171271**,

eliberat la **22.12.2010**, activând în baza **Statutului,**

să semneze si sa depuna din numele "COMERŢ-MAGOR" S.R.L., dosarele pentru inregistrarea dispozitivelor medicale la Agenţia Medicamentului şi Dispozitivelor Medicale. Dosarele urmeaza a fi depuse electronic, pentru urmatoarele proceduri de achizitie:

ocds-b3wdp1-MD-1694604660149 din 16.10.2023

Administrator
Semnătura

L.Ş.

COMERŢ CM MAGOR IDNO 1003600022518

Digitally signed by Cojocaru Vera
Date: 2023.10.16 10:39:28 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. **36** din **16/10/2023**

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 şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Numarul de catalog	Denumire	Modelul	Tip dispozitiv	Clasa de risc	Cod GMDN	Producător
42.03.10000	SET VALVĂ HEMOSTATICĂ	Twist Y Connector	Hemostasis Valve Set	Class-Is	36079	SCW MEDICATH LTD.
42.03.10005	SET VALVĂ HEMOSTATICĂ	Twist Y connector with 25cm extension line and stopcocks	Hemostasis Valve Set	Class-Is	36079	SCW MEDICATH LTD.
42.05.40003	DISPOZITIV COLECTOR DE PRESIUNE ÎNALTĂ	"OFF" Right-Handed w/Rotating Adapter, 3 Port, 250PSI	Manifold	Class-IIa	47258	SCW MEDICATH LTD.
42.04.40007	DISPOZITIV DE INFLAȚIE PENTRU CAETER CU BALON	Balloon inflation device, Stopcock("RIGHT OFF")+ Hemostasis valve set (Push Pull with 25cm extension line & stopcock)	Balloon Inflation Device	Class-Is	17541	SCW MEDICATH LTD.
42.17.30003	DISPOZITIV PENTRU HEMOSTAZA ARTEREI RADIALE	29 cm	Pressure Bandage	Class-Is	58704	SCW MEDICATH LTD.
42.17.30001	DISPOZITIV PENTRU HEMOSTAZA ARTEREI RADIALE	24 cm	Pressure Bandage	Class-Is	58704	SCW MEDICATH LTD.
42.03.10003	SET VALVĂ HEMOSTATICĂ	Push Pull Y connector with 45cm extension line and stopcocks	Hemostasis Valve Set	Class-Is	36079	SCW MEDICATH LTD.
42.16.10005	SERINGĂ PENTRU ADMINISTRARE INTRAVENOASĂ	DSA-200-A1	Angiographic Syringe	Class-IIa	15286	SCW MEDICATH LTD.
42.07.10002	SERINGĂ PENTRU ADMINISTRARE INTRAVENOASĂ	12ml Thumb Ring & Finger Rings	Dose-Control Syringe	Class-Is	15286	SCW MEDICATH LTD.

Se anexează următoarele acte:

a) declarația de conformitate CE emisă de producător pentru dispozitivele fabricate
b) certificatul de conformitate CE valabil pentru dispozitivele fabricate
c) actul prin care producătorul își desemnează reprezentantul

Data 16/10/2023 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: **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	Modelul	Tip dispozitiv	Clasa de risc	Cod GMDN	Producător
42.03.10000	SET VALVĂ HEMOSTATICĂ	Twist Y Connector	Hemostasis Valve Set	Class-Is	36079	SCW MEDICATH LTD.
42.03.10005	SET VALVĂ HEMOSTATICĂ	Twist Y connector with 25cm extension line and stopcocks	Hemostasis Valve Set	Class-Is	36079	SCW MEDICATH LTD.
42.05.40003	DISPOZITIV COLECTOR DE PRESIUNE ÎNALTĂ	"OFF" Right-Handed w/Rotating Adapter, 3 Port, 250PSI	Manifold	Class-IIa	47258	SCW MEDICATH LTD.
42.04.40007	DISPOZITIV DE INFLAȚIE PENTRU CAETER CU BALON	Balloon inflation device, Stopcock("RIGHT OFF")+ Hemostasis valve set (Push Pull with 25cm extension line & stopcock)	Balloon Inflation Device	Class-Is	17541	SCW MEDICATH LTD.
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42.17.30001	DISPOZITIV PENTRU HEMOSTAZA ARTEREI RADIALE	24 cm	Pressure Bandage	Class-Is	58704	SCW MEDICATH LTD.
42.03.10003	SET VALVĂ HEMOSTATICĂ	Push Pull Y connector with 45cm extension line and stopcocks	Hemostasis Valve Set	Class-Is	36079	SCW MEDICATH LTD.
42.16.10005	SERINGĂ PENTRU ADMINISTRARE INTRAVENOASĂ	DSA-200-A1	Angiographic Syringe	Class-IIa	15286	SCW MEDICATH LTD.
42.07.10002	SERINGĂ PENTRU ADMINISTRARE INTRAVENOASĂ	12ml Thumb Ring & Finger Rings	Dose-Control Syringe	Class-Is	15286	SCW MEDICATH LTD.

Sunt autentice și corespund realității.

Administrator Cojocaru Vladimir *Semnătura* _____

Data 16/10/2023

SuiteA1403,Longgang Tianan Cyber Park,Central Town, Longgang District 518172, Shenzhen,China
TEL: 86-755-89312160/ 89312258
FAX: 86-755-89312239

POWER OF ATTORNEY

The Company **SCW MEDICATH LTD.**, located at The CHINA (legal address: No.4 Baolong 6th Road Baolong Industrial Town Longgang District,Shenzhen 518116 Guangdong P.R.China) hereinafter called - «The Manufacturer», duly represented by the CEO, Steve Wang, acting under and by virtue of the Articles of Association.

By this power of attorney authorizes:

The Company **"Comert-Magor" S.R.L.,** Registration number: 1003600022518 located at str. Bucuriei 1, mun. 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 **SCW MEDICATH 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 get the Registration certificate issued in the name of **SCW MEDICATH LTD**

This power of attorney is granted for 1 **years**, with a right of substitution.

Date：2022-11-22

Sign：

SCW MEDICATH LTD.
深圳市益心达医学新技术有限公司

EC Certificate

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

TÜVRheinland®

Registration No.: HD 60144232 0001

Report No.: 17047213 010

Manufacturer:

SCW Medicath Ltd.
No. 4 Baolong 6th Road
Baolong Industrial Town
Longgang District, Shenzhen
518116 Guangdong
P.R. China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60139711 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: 2020-05-26

Date: 2020-05-26

Notified Body

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®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60144232 0001
Report No.: 17047213 010

Manufacturer:
SCW Medicath Ltd.
No. 4 Baolong 6th Road
Baolong Industrial Town
Longgang District, Shenzhen
518116 Guangdong
P.R. China

Products:

- Disposable Pressure Transducers
- Introducer Sets
- Guide Wires
- Angiographic Syringes
- Hemodialysis Catheterization Kits
- Patient-Controlled Analgesic Infusion Pumps
- Disposable Infusion Pumps
- Tracheostomy Tube Kits
- Percutaneous Nephrostomy Sets
- Ureteral Stent Sets
- Drainage Catheter Sets
- Transradial Introducer Sets
- Introducer Needles
- I.V Cannulas
- Cervical Ripening Balloon
- Postpartum Balloon

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-05-26

Fuxiu Sheng

TÜVRheinland®

Doc. 2/2, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60144232 0001
Report No.: 17047213 010

Manufacturer:
SCW Medicath Ltd.
No. 4 Baolong 6th Road
Baolong Industrial Town
Longgang District, Shenzhen
518116 Guangdong
P.R. China

Products:

- Locking Drainage Catheters
- Percutaneous Access Sets
- ERCP Guidewires
- Manifolds
- Stopcocks
- Manifold Sets
- Connecting Tubings

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Dose-control Syringes
- Balloon Inflation Devices
- Colored Piston Specialty Syringes
- Infusion Sets with Needleless Adapters
- Pressure Bandages
- Hemostasis Valve Sets
- Injection Caps

Notified Body

Date: 2020-05-26

Fuxiu Sheng

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

EC Declaration of Conformity

Manufacturer:

SCW MEDICATH LTD.

NO.4, Baolong 6th Road, Baolong Industrial Town, Longgang District, Shenzhen, 518116, Guangdong, P.R. China

whose single Authorized Representative:

OBELIS S.A.

Bd. Général Wahis 53
1030 Brussels, Belgium

We, the manufacturer, herewith declare that the products

Angiographic Syringes
Models: DSA-60-A1, DSA-150-A1, CT-100-X1, CT-200-A1, MRI-115-A1, DSA-100-B1, DSA-150-B1, CT-200-B1, MRI-65-A1, CT-200-A2, DSA-200-A1, DSA-130-A1, CT/DSA-150-B1, MRI-60-B1, CT-200-NE, DSA-90-NE, DSA-120-NE, CT-100-NE，CT-190-A1, CT-190/190-A1, CT-200/200-A2, CT-200/200-B1, CT-100/100-NE, CT-100/200-NE, CT-200/200-NE, CT-200-EM, CT-200/200-EM, CT-200-MED, CT-200/200-MED, MRI-65/115-A1, MRI-65/65-A1, MRI-115/115-A1, MRI-60/60-B1, MRI-60/60-NE, MRI-65-MED, MRI-65/200-MED
GMDN Code: 15286

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

The medical device has been assigned to class IIa according to Annex IX Rule 2 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
Deutschland
Certificate No.: HD 60144232 0001
Issue date: 26.05.2020
Expiry date: 26.05.2024

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

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

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

SCW MEDICATH LTD.
NO.4, Baolong 6th Road, Baolong Industrial Town,
Longgang District, Shenzhen, 518116, Guangdong, P.R. China

Miriam Xie

Shenzhen, 2022/09/23
Place, date

Legally binding signature, Function

EC Declaration of Conformity

Manufacturer:	*whose single Authorized Representative:*
SCW MEDICATH LTD.	**OBELIS S.A.**
NO.4, Baolong 6th Road, Baolong Industrial Town, Longgang District, Shenzhen, 518116, Guangdong, P.R. China	Bd. Général Wahis 53 1030 Brussels, Belgium

We, the manufacturer, herewith declare that the products

Balloon Inflation Devices

Models: SCW-BID-20, SCW-BID1-20, SCW-BID1-30, SCW-BID2-20

GMDN Code: 17541

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

The medical device has been assigned to class Is according to Annex IX Rule 2 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
Deutschland

Certificate No.: HD 60144232 0001
Issue date: 26.05.2020
Expiry date: 26.05.2024

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

For Class Is product only: Application of the abovementioned Annexes and the intervention by the Notified Body is limited to: the aspects of manufacture concerned with securing and maintaining sterile conditions.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

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

SCW MEDICATH LTD.
NO.4, Baolong 6th Road, Baolong Industrial Town,
Longgang District, Shenzhen, 518116, Guangdong, P.R. China

Miriam Xie

Shenzhen, 2022/09/21
Place, date

Legally binding signature, Function

EC Declaration of Conformity

Manufacturer:	*whose single Authorized Representative:*
SCW MEDICATH LTD.	**OBELIS S.A.**
NO.4, Baolong 6th Road, Baolong Industrial Town, Longgang District, Shenzhen, 518116, Guangdong, P.R. China	Bd. Général Wahis 53 1030 Brussels, Belgium

We, the manufacturer, herewith declare that the products

Dose-control Syringes

Models: SCW-CCS-0.25P, SCW-CCS-0.5P, SCW-CCS-001P, SCW-CCS-003P, SCW-CCS-006P, SCW-CCS-008P, SCW-CCS-010P, SCW-CCS-012P, SCW-CCS-020P, SCW-CCS-030P, SCW-CCS-060P

GMDN Code: 15286

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

The medical device has been assigned to class Is according to Annex IX Rule 2 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
Deutschland

Certificate No.: HD 60144232 0001
Issue date: 26.05.2020
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The above mentioned declaration of conformity is exclusively under the responsibility of

SCW MEDICATH LTD.
NO.4, Baolong 6th Road, Baolong Industrial Town,
Longgang District, Shenzhen, 518116, Guangdong, P.R. China

Shenzhen, 2022/09/22
Place, date

Miriam Xie
Legally binding signature, Function

EC Declaration of Conformity

Manufacturer:	*whose single Authorized Representative:*
SCW MEDICATH LTD.	**OBELIS S.A.**
NO.4, Baolong 6th Road, Baolong Industrial Town, Longgang District, Shenzhen, 518116, Guangdong, P.R. China	Bd. Général Wahis 53 1030 Brussels, Belgium

We, the manufacturer, herewith declare that the products

Hemostasis Valve Sets

Models: SCW-HV, SCW-HV-1, SCW-HV-2, SCW-HV-3, SCW-HV-4, SCW-HV-5, SCW-HV-6

GMDN Code: 36079

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

The medical device has been assigned to class Is according to Annex IX Rule 2 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
Deutschland

Certificate No.: HD 60144232 0001
Issue date: 26.05.2020
Expiry date: 26.05.2024

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

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This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

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

SCW MEDICATH LTD.
NO.4, Baolong 6th Road, Baolong Industrial Town,
Longgang District, Shenzhen, 518116, Guangdong, P.R. China

Miriam Xie

Shenzhen, 2022/09/21
Place, date

Legally binding signature, Function

EC Declaration of Conformity

Manufacturer:

SCW MEDICATH LTD.

NO.4, Baolong 6th Road, Baolong Industrial Town, Longgang District, Shenzhen, 518116, Guangdong, P.R. China

whose single Authorized Representative:

OBELIS S.A.

Bd. Général Wahis 53
1030 Brussels, Belgium

We, the manufacturer, herewith declare that the products

Manifolds
Models: One-Port, Two-Port, Three-Port, Four-Port, Five Port
GMDN Code: 47258

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

The medical device has been assigned to class IIa according to Annex IX Rule 2 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
Deutschland
Certificate No.: HD 60144232 0001
Issue date: 26.05.2020
Expiry date: 26.05.2024

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

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

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

SCW MEDICATH LTD.
NO.4, Baolong 6th Road, Baolong Industrial Town,
Longgang District, Shenzhen, 518116, Guangdong, P.R. China

Shenzhen, 2022/09/21
Place, date

Miriam Xie
Legally binding signature, Function

EC Declaration of Conformity

Manufacturer:	*whose single Authorized Representative:*
SCW MEDICATH LTD.	**OBELIS S.A.**
NO.4, Baolong 6th Road, Baolong Industrial Town, Longgang District, Shenzhen, 518116, Guangdong, P.R. China	Bd. Général Wahis 53 1030 Brussels, Belgium

We, the manufacturer, herewith declare that the products

Pressure Bandage

Models: SCW-ZXD-I, SCW-ZXD-II, SCW-ZXD-III, SCW-ZXD-IV

GMDN Code: 58704

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

The medical device has been assigned to class Is according to Annex IX Rule 1 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
Deutschland

Certificate No.: HD 60144232 0001
Issue date: 26.05.2020
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following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

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SCW MEDICATH LTD.
NO.4, Baolong 6th Road, Baolong Industrial Town,
Longgang District, Shenzhen, 518116, Guangdong, P.R. China

Shenzhen, 2022/09/21
Place, date

Miriam Xie
Legally binding signature, Function