Către Agenţia Medicamentului şi Dispozitivelor Medicale

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

Solicitantul **Dita Estfarm SRL**, cu sediul **str-la Burebistra 23, MD-2032, Chisinau, Republica Moldova**, tel./fax: **022 782 875**, e-mail: **irina.sandu@dita.md** 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 producătorului **BQ Plus Medical Co., Ltd., China:**

- Prelungitor
- Sistem pentru transfuzie cu dozator
- Prelungitor cu filtru
- Robinet tridirecțional

Digitally signed by Moraru Grigore
Date: 2023.09.17 09:02:20 EEST
Reason: MoldSign Signature
Location: Moldova

Se anexează următoarele acte:
- Actul de reprezentanță între producător și reprezentantul autorizat în Republica Moldova;
- Declarația de conformitate CE;
- Certificat de conformitate CE;
- Declarația pe propria răspundere a solicitantului;
- Lista dispozitivelor medicale (format Excel).

Data **07.09.2023** 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	Accept
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	Nr. 7355 din 11.09.2023
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	Clavadchi Dionisie
Semnătura persoanei responsabile	

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: **Dita Estfarm SRL**, cu sediul **str-la Burebistra 23, MD-2032, Chisinau, Republica Moldova**,

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 dispozitivelor medicale ale producatorului producătorului **BQ Plus Medical Co., Ltd., China:**

- Prelungitor
- Sistem pentru transfuzie cu dozator
- Prelungitor cu filtru
- Robinet tridirecțional

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia: *Semnătura* _____

RA-Manager – Sandu Irina *Data* ***07.09.2023***

We, BQ PLUS MEDICAL CO.,LTD ,

based in No.18 Cheye Rd, Chedun Tn,, Songjiang, Shanghai, China, 201611 , **assign Dita Estfarm LLC**, based in No.23 Burebista street, Chisinau MD -2032, Republic of Moldova, as **authorized representative** in correspondence with the conditions of Regulation (EU) 93/42.

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.

Place: Shanghai China Date: 01.08.2022

Signed:

BQ PLUS MEDICAL CO.,LTD 上海沙趣医疗科技有限公司 合同专用章

S.R.L. "DITA ESTFARM" IDNO 1002600046958

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60140269 0001

Report No.: 15080761 007

Manufacturer:
BQ Plus Medical Co., Ltd.
No. 18, Che Ye Road, Che Dun Town
Songjiang
201611 Shanghai
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60127717 0001

Expiry Date: 2024-05-27

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-08-19

Date: 2019-08-19

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. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60140269 0001
Report No.: 15080761 007

Manufacturer:
BQ Plus Medical Co., Ltd.
No. 18, Che Ye Road, Che Dun Town
Songjiang
201611 Shanghai
China

Products:

- Disposable Syringes
- Infusion Sets
- Transfusion Sets
- Burettes Transfusion Sets
- Extension Sets with or without Stopcock
- Three-way Stopcocks
- Flow Regulators
- Air Filters
- Heparin Caps
- Enteral Feeding Sets (Bags)
- Back Check Valves
- Liquid Filters
- Manifold
- Needle Free Valves
- Anesthesia Face Masks

Notified Body

Date: 2019-08-19

Fuxiu Sheng

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60140269 0001
Report No.: 15080761 007

Manufacturer:
BQ Plus Medical Co., Ltd.
No. 18, Che Ye Road, Che Dun Town
Songjiang
201611 Shanghai
China

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Medical Use Collecting Bags for Single Use
- Urinary Bags
- Enteral Syringes
- Disposable Luer Connectors

Date: 2019-08-19

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Fuxiu Sheng

BQ+
必趣医疗

EC-Declaration of Conformity

1. **Company Name & Address:**
   BQ Plus Medical Co., Ltd
   No. 18, Che Ye Road, Che Dun Town, Songjiang, 201611 Shanghai, China

2. **European Authorized Representative**
   Name: Prolinx GmbH
   Add: Brehmstr. 56, 40239, Duesseldorf
   Tel: 0049 0211 3105 4698
   E-mail: med@eulinx.eu

3. **Device Name and Variants:**
   Extension Sets with or without Stopcock

4. **Classification:** IIa (Annex IX per Rule 2)

5. **Conformity Assessment Route:** Directive 93/42/EEC Annex VII in connection with Annex V
   We hereby to certify that under our sole responsibility the above mentioned product conforms to the essential requirements of Council Directive 93/42/EEC and all the relevant EN harmonized standards. All related technical files have been filed by BQ Plus Medical Co., Ltd.

6. **Directives and Standards:**
   All applicable harmonized standards (published in the official Journal of the European Communities) and Council Directive 93/42/EEC.

7. **Notified Body:**
   TÜV Rheinland LGA Products GmbH
   Tillystrabe 2, 90431, Nürnberg, Germany
   CE 0197

8. **EC Certificate No.:** DD 6014 0269 0001
   Issue date: 2019-08-19
   Expiry date: 2024-05-27

S.R.L. "DITA ESTFARM" IDNO 1002600046559

Signature/Date: Eddie Zhang 2019.8.19 **Place:** Shanghai
Management Representative: Mr. Eddie Zhang

BQ+
必趣医疗

EC-Declaration of Conformity

1. **Company Name & Address:**
   BQ Plus Medical Co., Ltd
   No. 18, Che Ye Road, Che Dun Town, Songjiang, 201611 Shanghai, China

2. **European Authorized Representative**
   Name: Prolinx GmbH
   Add: Brehmstr. 56, 40239, Duesseldorf
   Tel: 0049 0211 3105 4698
   E-mail: med@eulinx.eu

3. **Device Name and Variants:**
   Infusion Sets
   Type: Infusion Sets for Gravity Feed

4. **Classification:** IIa (Annex IX per Rule 2)

5. **Conformity Assessment Route:** Directive 93/42/EEC Annex VII in connection with Annex V
   We hereby to certify that under our sole responsibility the above mentioned product conforms to the essential requirements of Council Directive 93/42/EEC and all the relevant EN harmonized standards. All related technical files have been filed by BQ Plus Medical Co., Ltd.

6. **Directives and Standards:**
   All applicable harmonized standards (published in the official Journal of the European Communities) and Council Directive 93/42/EEC.

7. **Notified Body:**
   TÜV Rheinland LGA Products GmbH
   Tillystrabe 2, 90431, Nürnberg, Germany
   CE 0197

8. **EC Certificate No.:** DD 6014 0269 0001
   Issue date: 2019-08-19
   Expiry date: 2024-05-27

S.R.L. "DITA ESTIFARM" IDNO 1002600046998

Signature/Date: Eddie Zhang 2021.05.20 **Place:** Shanghai
Management Representative: Mr. Eddie Zhang

BQ+
必趣医疗

EC-Declaration of Conformity

1. **Company Name & Address:**
   BQ Plus Medical Co., Ltd
   No. 18, Che Ye Road, Che Dun Town, Songjiang, 201611 Shanghai, China

2. **European Authorized Representative**
   Name: Prolinx GmbH
   Add: Brehmstr. 56, 40239, Duesseldorf
   Tel: 0049 0211 3105 4698
   E-mail: med@eulinx.eu

3. **Device Name and Variants:**
   Three-way Stopcocks

4. **Classification:** IIa (Annex IX per Rule 2)

5. **Conformity Assessment Route:** Directive 93/42/EEC Annex VII in connection with Annex V
   We hereby to certify that under our sole responsibility the above mentioned product conforms to the essential requirements of Council Directive 93/42/EEC and all the relevant EN harmonized standards. All related technical files have been filed by BQ Plus Medical Co., Ltd.

6. **Directives and Standards:**
   All applicable harmonized standards (published in the official Journal of the European Communities) and Council Directive 93/42/EEC.

7. **Notified Body:**
   TÜV Rheinland LGA Products GmbH
   Tillystrabe 2, 90431, Nürnberg, Germany
   CE 0197

8. **EC Certificate No.:** DD 6014 0269 0001
   Issue date: 2019-08-19
   Expiry date: 2024-05-27

S.R.L. "DITA ESTFARM" IDNO 1002600046359

Signature/Date: Eddie Zhang 2019.8.20 **Place:** Shanghai
Management Representative: Mr. Eddie Zhang

Nr.	Numărul de catalog (referinţă)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Prelungitor		Prelungitor	
2		Sistem pentru perfuzie cu dozator		Sistem pentru perfuzie cu dozator	
3		Prelungitor cu filtru		Prelungitor cu filtru	
4		Robinet tridirecțional		Robinet tridirecțional