

Către Agenția Medicamentului și 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 și 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

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	Clara Techi Dionisie
Semnătura persoanei responsabile	CTD

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. **352¹**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivelor medicale ale producătorului 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 și funcția:

RA-Manager – Sandu Irina

Semnătura _____



Data 07.09.2023

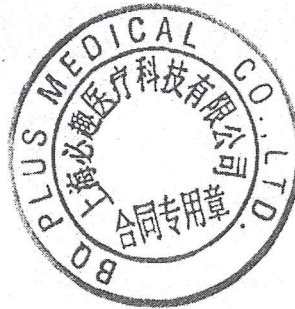
We, BQ PLUS MEDICAL CO.,LTD,

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: *Laurus*





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)

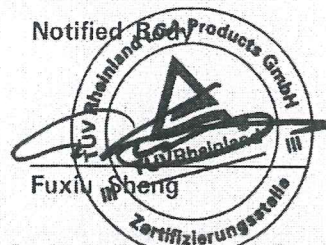
Replaces Approval, Registration No.: DD 60127717 0001

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



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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/2, Rev. 0

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



Date: 2019-08-19

Notified Body
TÜV Rheinland LGA Products GmbH
Fuxiu She
Zertifizierungsstelle





TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

**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



Fuxiu Sheng

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

Signature/Date: Eddie Zhang 2024.05.10
Management Representative: Mr. Eddie Zhang

Place: Shanghai

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: Prolix 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.

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CE 0197

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Issue date: 2019-08-19

Expiry date: 2024-05-27



Signature/Date: Eddie Zhang 2022.05.20
Management Representative: Mr. Eddie Zhang

Place: Shanghai

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BQ Plus Medical Co., Ltd

No. 18, Che Ye Road, Che Dun Town, Songjiang, 201611 Shanghai, China

2. European Authorized Representative

Name: Prolix 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.

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Expiry date: 2024-05-27



Signature/Date: Eddie Zhang 2024-05-27 Place: Shanghai
Management Representative: Mr. Eddie Zhang

Nr.	Numărul de catalog (referință)*	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	

