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 **Jiangsu Jichun Medical Devices Co., Ltd., China:**

- Prelungitor pentru sisteme infuzie

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 **15.09.2023** 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	

Digitally signed by Moraru Grigore
Date: 2023.09.17 11:03:13 EEST
Reason: MoldSign Signature
Location: Moldova

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 **Jiangsu Jichun Medical Devices Co., Ltd., China:**

- Prelungitor pentru sisteme infuzie

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia: *Semnătura*

RA-Manager – Sandu Irina *Data* ***15.09.2023***

江苏吉春医用器材有限公司
Jiangsu Jichun Medical Devices Co.,Ltd.
Tel/Fax:+86-519-88906510 http://www.chinajichun.com
Add:Zhenglu Town,Changzhou City,Jiangsu Province,China

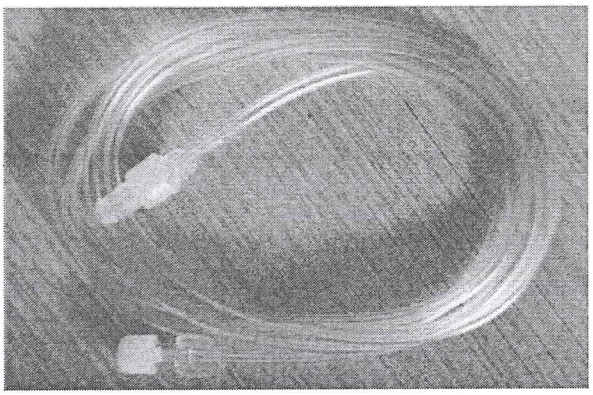
We, Jiangsu Jichun Medical Devices Co.,Ltd.,based in No.98 Baiyang Bridge,Zhenglu Town,Tianning,Changzhou,213111 Jiangsu,P.R china, **assign Dita Estfarm LLC**, based in No.23 Burebista street, Chisinau MD -2032, Republic of Moldova, as **authorized representative** in correspondence with the conditions of Regulation (EU) 2017/745.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of the below product on the territory of the Republic of Moldova.

Place: _____ Date: Sep 13th, 2023

Signed: _____

1. sterile
2. length: 150 cm
3. material: PVC, transparent
4. For single use
5. individual packaging
6. Connector: Luer-Lock
7. Remaining shelf life (at delivery time) - 3 years



EU Certificate

Production Quality Assurance
REGULATION (EU) 2017/745 on Medical Devices, Annex XI, Part A

TÜVRheinland®

Registration No.:	DZ 2049691-1
Manufacturer:	**Jiangsu Jichun Medical Devices Co., Ltd.** No.98 Baiyang Bridge, Zhenglu Town, Tianning, Changzhou, 213111 Jiangsu, P.R. China
EUDAMED Single Registration No.:	CN-MF-000019298
Products:	Products of class IIa: A010101 - HYPODERMIC NEEDLES - Disposable Hypodermic Needles - Disposable Safety Hypodermic Needles - Disposable Insulin Pen Needles A010102 - BUTTERFLY NEEDLES - Disposable Scalp Vein Sets A020102 - INFUSION AND IRRIGATION DISPOSABLE SYRINGES - Disposable Syringes - Disposable Safety Syringes A020106 - SINGLE-USE INSULIN SYRINGES - Disposable Insulin Syringes A030101 - INFUSION CONTROLLERS - Disposable Burette Infusion Sets - Disposable Infusion Sets - Disposable Transfusion Sets - Disposable Transfusion Sets without Needle Products of class I, sterile: A030201 - EXTENSIONS - Disposable Extension Sets A0703 - STOPCOCKS - 3-way Stop Cocks

SOCIETATEA CU RĂSPUNDERE LIMITATĂ, REPUBLICA MOLDOVA, mun. CHIȘINĂU
S.R.L.
"DITA ESTFARM"
IDNO 1002600046359
18

The Notified Body hereby declares that the requirements of Annex XI, Part A of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a production quality assurance, which is subject to periodic surveillance, defined by Annex XI, Part A, Section 7 of the aforementioned regulation. If class III devices or class IIb devices are covered by this certificate, an EU type-examination certificate in accordance with Annex X of the aforementioned regulation is required before placing them on the market.

Report No.:	244420156-200
Effective date:	2022-12-30
Expiry date:	2027-12-29
Issue date:	2022-12-30

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle
TÜVRheinland®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

EU Certificate

Production Quality Assurance
REGULATION (EU) 2017/745 on Medical Devices, Annex XI, Part A

TÜVRheinland®

Registration No.: DZ 2049691-1

Manufacturer: **Jiangsu Jichun Medical Devices Co., Ltd.**
No.98 Baiyang Bridge, Zhenglu Town, Tianning,
Changzhou, 213111 Jiangsu,
P.R. China

A020108 - SYRINGES FOR ENTERAL FEEDING
- Disposable Enteral Feeding Syringes
T020603 - MEDICAL USE FACE MASKS, TYPE I (NOT FOR HEALTHCARE PROFESSIONALS)
- Disposable Medical Face Masks
A020604 - MEDICAL USE FACE MASKS, TYPE II AND IIR
- Disposable Medical Face Masks
A020102 - INFUSION AND IRRIGATION DISPOSABLE SYRINGES
- Disposable Syringes without Needle
- Disposable Syringes with Catheter Tips
A030101 - INFUSION CONTROLLERS
- Disposable Burette Infusion Sets without needle
- Disposable Infusion Sets without needle

For class I sterile device(s) covered in the scope, the certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

Authorised representative(s): **Caretechion GmbH**
Niederrheinstr. 71 40474 Düsseldorf, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial revision	2022-12-30

S.R.L. "DITA ESTFARM" ONG 1002600046359 SOCIETATEA CU RĂSPUNDERE LIMITATĂ, REPUBLICA MOLDOVA, mun. CHIȘINĂU 18

Report No.: 244420156-200

Effective date: 2022-12-30

Expiry date: 2027-12-29

Issue date: 2022-12-30

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de BS-MDR-091

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: /	**Jiangsu Jichun Medical Devices Co., Ltd.** **No. 98, Baiyang Bridge, Zhenglu Town, Tianning, Changzhou, Jiangsu 213111, China** **SRN:CN-MF-000019298**
Registered trade name or mark:/	**Disposable Extension Sets**
EC Authorized Representative:/	**Caretechion GmbH** **Niederrheinstr. 71 40474 Düsseldorf, Germany** **SRN: DE-AR-000005946**

We declare under our sole responsibility that

Name of the medical device: /	**Disposable Extension Sets** **A、B**
Product code:/	**EMDN code: A030201 EXTENSIONS**
Intended purpose: /	**Intravenous infusion of liquid medicine for human body after being matched with an infusion device.**
Basic UDI-DI:/	**69586949GLJG0016T**
CS reference: /	**NONE**
of class: / According to annex VIII of Regulation (EU) 2017/745 /	**Rule 2, Class Is**
Conformity assessment procedure:/	**MDR Annex XI Part A**
Notified Body: /	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2, 90431 Nürnberg Germany**
NB Identification number: /	**CE0197**
Certificate No.:/	**DZ 2049691-1**

Meets the provisions of the Regulation (EU) 2017/745 and other relevant Union legislation which apply to it.
The declaration is valid in connection with the "final inspection report" of the device. /

Changzhou 2023.1.3

Ort, Datum / Place, date /
Lieu, date / Luogo, data

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione

Nr.	Numărul de catalog (referinţă)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Prelungitor pentru sisteme infuzie