

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 producătorului **Beijing Target Medical Technologies Inc., China:**

- Cateter Venos Central Monolumen, 14G 15cm
- Cateter Venos Central Monolumen, 14G 20cm
- Cateter Venos Central Monolumen, 14G 30cm
- Cateter Venos Central Monolumen, 16G 15cm
- Cateter Venos Central Monolumen, 16G 20cm
- Cateter Venos Central Monolumen, 16G 30cm
- Cateter Venos Central Monolumen, 18G 15cm
- Cateter Venos Central Monolumen, 18G 20cm
- Cateter Venos Central Monolumen, 18G 30cm
- Cateter Venos Central Monolumen, 20G 13cm
- Cateter Venos Central Monolumen, 20G 20cm

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. 7350 din 11.09.2023 |
| Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului | Clavatechi Dionisie |
| Semnătura persoanei responsabile | CDJ |

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 **Beijing**

Target Medical Technologies Inc., China:

- Cateter Venos Central Monolumen, 14G 15cm
- Cateter Venos Central Monolumen, 14G 20cm
- Cateter Venos Central Monolumen, 14G 30cm
- Cateter Venos Central Monolumen, 16G 15cm
- Cateter Venos Central Monolumen, 16G 20cm
- Cateter Venos Central Monolumen, 16G 30cm
- Cateter Venos Central Monolumen, 18G 15cm
- Cateter Venos Central Monolumen, 18G 20cm
- Cateter Venos Central Monolumen, 18G 30cm
- Cateter Venos Central Monolumen, 20G 13cm
- Cateter Venos Central Monolumen, 20G 20cm

Sunt autentice și corespund realității.

Numele, prenumele și funcția:

RA-Manager – Sandu Irina

Semnătura _____



Data 07.09.2023



北京天地和协科技有限公司
Beijing Target Medical Technologies, Inc.

Letter of Authorization

We **Beijing Target Medical Technologies, Inc** based in No.60, Shunren Road, Shunyi District, Beijing, 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) 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: Beijing

Date: 05.09.2023

Signed:



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 ZLG-BS-244.10.08



Product Service

EC Certificate

EC Design-Examination Certificate
 Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
 (Devices in Class III)

No. G7 073322 0014 Rev. 01

Model(s): Disposable central venous catheter kit

Parameter: Size Range:

Single Lumen: 14G-20G(OD:1.05-2.1mm)
 Double Lumen: 4F-11.5F(OD:1.35-3.85mm)
 Triple Lumen: 5.5F-7F(OD:1.85-2.35mm)
 Length of Tubing: 50-600mm



Model List

| Model | CVC | | | guide wire | Dilator | Introducer needle | Catheter Clamp |
|----------------|-------|------------|----------------------|------------|---------|-------------------|----------------|
| | Lumen | OD/ G or F | Effective length /mm | | | | |
| MMCVCBJ1-14-15 | 1 | 14G | 150 | 35060 | 8F | 1870 | Φ2.1 |
| MMCVCBJ1-14-20 | 1 | 14G | 200 | 35060 | 8F | 1870 | Φ2.1 |
| MMCVCBJ1-14-30 | 1 | 14G | 300 | 35070 | 8F | 1870 | Φ2.1 |
| MMCVCBJ1-16-15 | 1 | 16G | 150 | 35060 | 7F | 1870 | Φ1.5 |
| MMCVCBJ1-16-20 | 1 | 16G | 200 | 35060 | 7F | 1870 | Φ1.5 |
| MMCVCBJ1-16-30 | 1 | 16G | 300 | 35070 | 7F | 1870 | Φ1.5 |
| MMCVCBJ1-18-15 | 1 | 18G | 150 | 21060 | 5F | 2038 | Φ1.3 |
| MMCVCBJ1-18-20 | 1 | 18G | 200 | 21060 | 5F | 2038 | Φ1.3 |
| MMCVCBJ1-18-30 | 1 | 18G | 300 | 21060 | 5F | 2038 | Φ1.3 |
| MMCVCBJ1-20-13 | 1 | 20G | 130 | 21060 | 5F | 2038 | Φ1.0 |
| MMCVCBJ1-20-20 | 1 | 20G | 200 | 21060 | 5F | 2038 | Φ1.0 |
| MMCVCBJ1-40-45 | 1 | 4F | 450 | 21060 | 5F | 2038 | Φ1.0 |
| MMCVCBJ1-40-60 | 1 | 4F | 600 | 21070 | 5F | 2038 | Φ1.0 |
| MMCVCBJ1-50-45 | 1 | 5F | 450 | 21060 | 6F | 2038 | Φ1.3 |
| MMCVCBJ1-50-60 | 1 | 5F | 600 | 21070 | 6F | 2038 | Φ1.3 |
| MMCVCBJ2-40-05 | 2 | 4F | 50 | 21060 | 5F | 2038 | Φ1.3 |
| MMCVCBJ2-40-08 | 2 | 4F | 80 | 21060 | 5F | 2038 | Φ1.3 |

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Product Service

EC Certificate

EC Design-Examination Certificate
 Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
 (Devices in Class III)

No. G7 073322 0014 Rev. 01

| | | | | | | | |
|-----------------|--|-------|-----|-------|-----|------|------|
| MMCVCBJ2-40-13 | 2 | 4F | 130 | 21060 | 5F | 2038 | Φ1.3 |
| MMCVCBJ2-50-08 | 2 | 5F | 80 | 21060 | 6F | 2038 | Φ1.7 |
| MMCVCBJ2-50-13 | 2 | 5F | 130 | 21060 | 6F | 2038 | Φ1.7 |
| MMCVCBJ2-50-20 | 2 | 5F | 200 | 21060 | 6F | 2038 | Φ1.7 |
| MMCVCBJ2-70-15 | 2 | 7F | 150 | 35060 | 8F | 1870 | Φ2.3 |
| MMCVCBJ2-70-20 | 2 | 7F | 200 | 35060 | 8F | 1870 | Φ2.3 |
| MMCVCBJ2-70-30 | 2 | 7F | 300 | 35070 | 8F | 1870 | Φ2.3 |
| MMCVCBJ2-70-50 | 2 | 7F | 500 | 35070 | 8F | 1870 | Φ2.3 |
| MMCVCBJ2-115-13 | 2 | 11.5F | 130 | 35060 | 12F | 1870 | / |
| MMCVCBJ2-115-16 | 2 | 11.5F | 160 | 35060 | 12F | 1870 | / |
| MMCVCBJ2-115-20 | 2 | 11.5F | 200 | 35060 | 12F | 1870 | / |
| MMCVCBJ3-55-08 | 3 | 5.5F | 80 | 21060 | 6F | 2038 | Φ1.7 |
| MMCVCBJ3-55-13 | 3 | 5.5F | 130 | 21060 | 6F | 2038 | Φ1.7 |
| MMCVCBJ3-70-15 | 3 | 7F | 150 | 35060 | 8F | 1870 | Φ2.3 |
| MMCVCBJ3-70-20 | 3 | 7F | 200 | 35060 | 8F | 1870 | Φ2.3 |
| MMCVCBJ3-70-30 | 3 | 7F | 300 | 35070 | 8F | 1870 | Φ2.3 |
| Note | All models include the following accessories: Scalpel (11#), Syringe (5ml), Blue introducer syringe (5ml), Rigid fastener, Stanch Clip, Heparin cap. | | | | | | |





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Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
 (Devices in Class IIa, IIb or III)

No. G1 073322 0018 Rev. 01

Facility(ies):

Beijing Target Medical Technologies Inc.
 No.60, Shunren Rd., Shunyi District, 101300 Beijing, PEOPLE'S
 REPUBLIC OF CHINA



TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC (INCLUDING 2007/47/EC) CONCERNING MEDICAL DEVICES



MANUFACTURER:

BEIJING TARGET MEDICAL TECHNOLOGIES INC.
No. 60, SHUNREN RD., SHUNYI DISTRICT, BEIJING, 102200, P.R. CHINA
TEL.: 86 10-89493813/2512 FAX: 86 10-89419091/80120615

**MEDICAL DEVICE:
UMDNS CODES**

DISPOSABLE CENTRAL VENOUS CATHETER KIT
16615

CLASSIFICATION - ANNEX IX:

CLASS III, RULE 7, ANNEX IX, MDD

CONFORMITY ASSESSMENT ROUTE: ANNEX II

WE, BEIJING TARGET MEDICAL TECHNOLOGIES, INC., HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC (INCLUDING 2007/47/EC) CONCERNING MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER. WE, AS THE MANUFACTURER, ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED:

EN ISO 13485:2016+A11:2021; EN ISO 14971:2019/A11:2021; MEDDEV 2.7.1 REV. 4 ;
EN ISO 20417:2021; EN ISO 10555-1:2013/A1:2017 ; ISO 10555-3:2013;
EN ISO 10993-1:2020; EN ISO 10993-3:2014; EN ISO 10993-4:2017, EN ISO 10993-5:2009;
EN ISO 10993-6:2016; EN ISO 10993-7:2008/A1:2022; EN ISO 10993-10:2023;
EN ISO 10993-11: 2018; EN ISO 10993-18:2009; EN ISO 11607-1:2020/A11:2022;
EN ISO 11737-1:2018/A1:2021; EN ISO 8536-4:2020; EN ISO 11070-2014+A1:2018; EN ISO 7886-1:2018;
EN 556-1:2001/AC: 2006; EN ISO 80369-7:2021; EN ISO 11135:2014+A1:2019; EN ISO 7864-2016

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTRABE 65, D-80339 MÜNCHEN, GERMANY

**IDENTIFICATION NUMBER
(EC) CERTIFICATE(S):**

CE 0123
G1 073322 0018 REV.01
G7 073322 0014 REV.01

EC REP

EUROPEAN REPRESENTATIVE:

LEPU MEDICAL (EUROPE) COÖPERATIEF U.A.
ADD: ABE LENSTRA BOULEVARD 36, 8448 JB, HEERENVEEN,
THE NETHERLANDS . TEL.: +31-515-573399,
FAX: +31-515-760020

START OF CE-MARKING:

PLACE, DATE OF DECLARATION:

BEIJING, 2022.12.28

SIGNATURE:

Wang Jianping
NAME: MR. WANG JIANPING
POSITION: MANAGEMENT REPRESENTATIVE



**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC (INCLUDING
2007/47/EC) CONCERNING MEDICAL DEVICES**

MODEL AS BELOW

| | | | |
|----------------|-----------------|-----------------|-----------------|
| MMCVCBJ1-14-15 | MMCVCBJ1-14-20 | MMCVCBJ1-14-30 | MMCVCBJ1-16-15 |
| MMCVCBJ1-16-20 | MMCVCBJ1-16-30 | MMCVCBJ1-18-15 | MMCVCBJ1-18-20 |
| MMCVCBJ1-18-30 | MMCVCBJ1-20-13 | MMCVCBJ1-20-20 | MMCVCBJ1-40-45 |
| MMCVCBJ1-40-60 | MMCVCBJ1-50-45 | MMCVCBJ1-50-60 | MMCVCBJ2-40-05 |
| MMCVCBJ2-40-08 | MMCVCBJ2-40-13 | MMCVCBJ2-50-08 | MMCVCBJ2-50-13 |
| MMCVCBJ2-50-20 | MMCVCBJ2-70-15 | MMCVCBJ2-70-20 | MMCVCBJ2-70-30 |
| MMCVCBJ2-70-50 | MMCVCBJ2-115-13 | MMCVCBJ2-115-16 | MMCVCBJ2-115-20 |
| MMCVCBJ3-55-08 | MMCVCBJ3-55-13 | MMCVCBJ3-70-15 | MMCVCBJ3-70-20 |
| MMCVCBJ3-70-30 | | | |



| Nr. | Numărul de catalog (referință)* | Denumire generică (denumirea dispozitivului) | Denumire comercială (brand)* | Modelul | Cod GMDN* |
|-----|---------------------------------|--|------------------------------|----------|-----------|
| 1 | | Cateter Venos Central Monolumen | | 14G 15cm | |
| 2 | | Cateter Venos Central Monolumen | | 14G 20cm | |
| 3 | | Cateter Venos Central Monolumen | | 14G 30cm | |
| 4 | | Cateter Venos Central Monolumen | | 16G 15cm | |
| 5 | | Cateter Venos Central Monolumen | | 16G 20cm | |
| 6 | | Cateter Venos Central Monolumen | | 16G 30cm | |
| 7 | | Cateter Venos Central Monolumen | | 18G 15cm | |
| 8 | | Cateter Venos Central Monolumen | | 18G 20cm | |
| 9 | | Cateter Venos Central Monolumen | | 18G 30cm | |
| 10 | | Cateter Venos Central Monolumen | | 20G 13cm | |
| 11 | | Cateter Venos Central Monolumen | | 20G 20cm | |

