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 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. 7356 din 11.09.2023
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	Clovatchi Dionisie
Semnătura persoanei responsabile	CDS

Digitally signed by Moraru Grigore
Date: 2023.09.17 11:59:47 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 declaraţii, că documentele și datele furnizate pentru notificarea dispozitivelor medicale ale producatorului 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 şi funcţia: *Semnătura* _____

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

Target Medical

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:

北京市顺义区顺仁路 60 号 电话：010-89493813 传真：010-89419091 邮编：101300 Http://www.tepumedical.com
Add.: No.60, Shunren Rd., Shunyi District, Beijing 101300, P.R. China Tel: +86 1089493813 Fax: +86 1089419091

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

Manufacturer:

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

Product:

Catheter for Cardiology and Angioplasty
Disposable central venous catheter kit

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: BJ1871106

Valid from: 2020-04-09
Valid until: 2024-05-26

Date, 2020-04-09

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV SÜD 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

REPUBLICA MOLDOVA, CHISINAU, S.R.L. "DITA ESTFARM" IDNO 1002600046359, SOCIETATEA CU RASPUNDERE LIMITATA

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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV SÜD 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.						

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

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TÜV SÜD 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

Manufacturer:

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

Product Category(ies): **Disposable Introducer Kit, Disposable Central Venous Catheter Kit, Disposable Blood Pressure Transducer, Arterial Blood Sampling Kits.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: BJ19071103

Valid from: 2020-01-03
Valid until: 2024-05-14

Date, 2020-01-03

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV SÜD 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 Product Service GmbH is Notified Body with identification no. 0123

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*

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

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			

Ref: EN ISO/IEC 17050-1

revision date: June 2009

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