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 **Changsha Renji Medical Equipment Co., Ltd., China:**

- Ansă bacteriologică 10µl
- Bastonașe de sticlă
- Eprubete pentru recoltarea sângelui, K3EDTA 0,1ml
- Container nesteril mase fecale 30ml
- Container steril mase fecale 30ml
- Container steril spută 30ml
- Cutie Petri 120x120mm
- Eprubete cu vacuum pentru recoltarea sângelui, Citrat de sodiu 2,7ml
- Eprubete cu vacuum pentru recoltarea sângelui, VSH 3,6ml
- Eprubete cu vacuum pentru recoltarea sângelui, Activator de coagulare 4,5ml
- Spatulă bacteriologică sterilă forma L
- Cameră pentru calcularea sedimentului urinar

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

Data **23.08.2023** 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	

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 **Changsha Renji Medical Equipment Co., Ltd., China:**

- Ansă bacteriologică 10µl
- Bastonașe de sticlă
- Eprubete pentru recoltarea sângelui, K3EDTA 0,1ml
- Container nesteril mase fecale 30ml
- Container steril mase fecale 30ml
- Container steril spută 30ml
- Cutie Petri 120x120mm
- Eprubete cu vacuum pentru recoltarea sângelui, Citrat de sodiu 2,7ml
- Eprubete cu vacuum pentru recoltarea sângelui, VSH 3,6ml
- Eprubete cu vacuum pentru recoltarea sângelui, Activator de coagulare 4,5ml
- Spatulă bacteriologică sterilă forma L
- Cameră pentru calcularea sedimentului urinar

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia:

RA-Manager – Sandu Irina

Semnătura _____

Data ***23.08.2023***

We, **Changsha Renji Medical Equipment Co.,Ltd** , based in Building 8, No18 Xiangtai Road, Changsha E Center, Liuyang Jingkai District, Changsha City, Hunan Province, 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 if Regulation 2017/746.

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: Changsha City, Hunan Province, China. Date: 02.12.2022

Signed: Vivien Wang

EU DECLARATION OF CONFORMITY

According to Article 17 of Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices

Manufacturer:	Changsha Renji Medical Equipment Co., Ltd. 201, Stage 4, Changsha E Center, No.18 Xiangtai Road, Liuyang Jingkai District, Changsha City, 410300,Hunan Province, China
SRN:	CN-MF-000030318
European Representative:	MedUnion S.L. Carrer de Tapioles, 33, 2-1, 08004, Barcelona, Spain
SRN:	ES-AR-000019366
Product Name:	Sample Container
Product Model:	Biological Sample Container, Histological Tissue Container, Sputum container
Product Specification:	1mL, 2mL, 5mL, 10ml, 30ml, 50mL, 100mL, 2500mL, 5000mL, 265x189x142
Intended Use:	For the collection, storage and transport of samples for subsequent examination of human biological fluids, secretions, solid substances, etc. Medical device for in vitro diagnostics.
EMDN:	W05019099
Basic UDI-DI:	697547397040030005ZV
Classification acc. to IVDR Ax. VIII:	Class A , Rule 5 (b) of IVDR Annex Ⅷ
Conformity Assessment Procedure:	Article 48 (10), IVDR (EU) 2017/746
STANDARDS APPLIED:	EN ISO 14971:2019 / EN ISO 18113-1:2013 / EN 13612:2002 EN ISO 13485:2016 / EN ISO 18113-2:2013 / EN 62366:2015 EN ISO 23640:2016 / EN ISO 15223-1:2016 / EN 13641:2015 ISO/TR 24971:2020 / ISO 20916:2019 / EN 14820:2004

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR). All supporting documentations are retained under the premises of the manufacturer.

China
Oct 1, 2022
Place, date

CHANGSHA RENJI MEDICAL EQUIPMENT CO.,LTD.

CEO Renjiang Li
Legally binding signature, Function

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

EU DECLARATION OF CONFORMITY

According to Article 17 of Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices

Manufacturer:	Changsha Renji Medical Equipment Co., Ltd. 201, Stage 4, Changsha E Center, No.18 Xiangtai Road, Liuyang Jingkai District, Changsha City, 410300,Hunan Province, China
SRN:	CN-MF-000030318
European Representative:	MedUnion S.L.
SRN:	Carrer de Tapioles, 33, 2-1, 08004, Barcelona, Spain ES-AR-000019366
Product Name:	Blood Collection Tube
Product Model:	100 tests/kit
Intended Use:	Blood Collection Tube is used to collect, transport, store and process blood for testing serum, plasma or whole blood in the clinical laboratory and are for professional use.To be used in conjunction with a disposable blood collection needle. Blood Collection Tube and Needles are used together as a system for the collection of venous blood.
EMDN:	W0501010102
Basic UDI-DI:	697547397030010001YC
Classification acc. to IVDR Ax. VIII:	Class A , Rule 5 (b) of IVDR Annex VIII
Conformity Assessment Procedure:	Article 48 (10), IVDR (EU) 2017/746

STANDARDS APPLIED:

EN ISO 14971:2019	EN ISO 18113-1:2013	EN 13612:2002
EN ISO 13485:2016	EN ISO 18113-2:2013	EN 62366:2015
EN ISO 23640:2016	EN ISO 15223-1:2016	EN 13641:2015
ISO/TR 24971:2020	ISO 20916:2019	EN 14820:2004

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR). All supporting documentations are retained under the premises of the manufacturer.

China
Oct 1, 2022
Place, date

Renjiang Li
CEO
Legally binding signature, Function

EU DECLARATION OF CONFORMITY

According to Article 17 of Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices

Manufacturer:	Changsha Renji Medical Equipment Co., Ltd. 201, Stage 4, Changsha E Center, No.18 Xiangtai Road, Liuyang Jingkai District, Changsha City, 410300,Hunan Province, China
SRN:	CN-MF-000030318
European Representative:	MedUnion S.L. Carrer de Tapioles, 33, 2-1, 08004, Barcelona, Spain
SRN:	ES-AR-000019366
Product Name:	Disposable Stool Container
Product Model:	RJ- Ⅰ ; RJ- Ⅱ ; RJ- Ⅲ
Intended Use:	This product is suitable for the laboratory of medical institutions to collect , transport and store stool.
EMDN:	W05019099
Basic UDI-DI:	697547397040030001ZM
Classification acc. to IVDR Ax. VIII:	Class A , Rule 5 (b) of IVDR Annex Ⅷ
Conformity Assessment Procedure:	Article 48 (10), IVDR (EU) 2017/746
STANDARDS APPLIED:	EN ISO 14971:2019 / EN ISO 18113-1:2013 / EN 13612:2002 EN ISO 13485:2016 / EN ISO 18113-2:2013 / EN 62366:2015 EN ISO 23640:2016 / EN ISO 15223-1:2016 / EN 13641:2015 ISO/TR 24971:2020 / ISO 20916:2019 / EN 14820:2004

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR). All supporting documentations are retained under the premises of the manufacturer.

China
Oct 1, 2022
Place, date

CHANGSHA RENJI MEDICAL EQUIPMENT CO.,LTD.

CEO Renjiang Li
Legally binding signature, Function

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

EU DECLARATION OF CONFORMITY

According to Article 17 of Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices

Manufacturer:	Changsha Renji Medical Equipment Co., Ltd. 201, Stage 4, Changsha E Center, No.18 Xiangtai Road, Liuyang Jingkai District, Changsha City, 410300,Hunan Province, China
SRN:	CN-MF-000030318
European Representative:	MedUnion S.L. Carrer de Tapioles, 33, 2-1, 08004, Barcelona, Spain
SRN:	ES-AR-000019366
Product Name:	Glass Rod
Product Model:	Length 200-250mm. diameter 5-7mm.
Intended Use:	Clear Stir Stick is made of borosilicate glass material, it's widely used in mixing chemicals and liquids in laboratory use

Classification acc. to IVDR Ax. VIII:	Class A , Rule 5 (b) of IVDR Annex Ⅷ
Conformity Assessment Procedure:	Article 48 (10), IVDR (EU) 2017/746

STANDARDS APPLIED:

EN ISO 14971:2019	EN ISO 18113-1:2013	EN 13612:2002
EN ISO 13485:2016	EN ISO 18113-2:2013	EN 62366:2015
EN ISO 23640:2016	EN ISO 15223-1:2016	EN 13641:2002
ISO/TR 24971:2020	ISO 20916:2019	EN 14820:2004

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR). All supporting documentations are retained under the premises of the manufacturer.

Oct 1,2022 China

Place, date

CHANGSHA RENJI MEDICAL EQUIPMENT CO.,LTD.

Renjiang Li

Legally binding signature, Function

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

EU DECLARATION OF CONFORMITY

According to Article 17 of Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices

Manufacturer:	Changsha Renji Medical Equipment Co., Ltd. 201, Stage 4, Changsha E Center, No.18 Xiangtai Road, Liuyang Jingkai District, Changsha City, 410300,Hunan Province, China
SRN:	CN-MF-000030318
European Representative:	MedUnion S.L. Carrer de Tapioles, 33, 2-1, 08004, Barcelona, Spain
SRN:	ES-AR-000019366
Product Name:	Inoculation Loop
Product Model:	10μL, Φ2mm, Φ4mm
Intended Use:	For quantitative procedures such as sampling, serial dilutions and urine counts, as well as for bacterial inoculation.

Classification acc. to IVDR Ax. VIII:	Class A , Rule 5 (b) of IVDR Annex Ⅷ
Conformity Assessment Procedure:	Article 48 (10), IVDR (EU) 2017/746

STANDARDS APPLIED:

EN ISO 14971:2019	EN ISO 18113-1:2013	EN 13612:2002
EN ISO 13485:2016	EN ISO 18113-2:2013	EN 62366:2015
EN ISO 23640:2016	EN ISO 15223-1:2016	EN 13641:2002
ISO/TR 24971:2020	ISO 20916:2019	EN 14820:2004

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR). All supporting documentations are retained under the premises of the manufacturer.

Oct 1,2022 China

Place, date

CHANGSHA RENJI MEDICAL EQUIPMENT CO.,LTD.

Renjiang Li

Legally binding signature, Function

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

EU DECLARATION OF CONFORMITY

According to Article 17 of Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices

Manufacturer:	Changsha Renji Medical Equipment Co., Ltd. 201, Stage 4, Changsha E Center, No.18 Xiangtai Road, Liuyang Jingkai District, Changsha City, 410300,Hunan Province, China
SRN:	CN-MF-000030318
European Representative:	MedUnion S.L. Carrer de Tapioles, 33, 2-1, 08004, Barcelona, Spain
SRN:	ES-AR-000019366
Product Name:	Petri Dish
Product Model:	Round: Φ35mm, Φ60mm, Φ70mm, Φ90mm, Φ150mm Square: 100mm×100mm, 120mm×120mm
Intended Use:	Petri dishes are used for the transport, storage and collection of biological specimens (e.g. cells, tissue specimens, urine, faeces, etc.) and are suitable for the aerobic and/or anaerobic general growth of organisms or micro-organisms when added to a suitable medium for in vitro diagnostic use.
EMDN:	W0503030101
Basic UDI-DI:	6975473970400500012E
Classification acc. to IVDR Ax. VIII:	Class A , Rule 5 (b) of IVDR Annex Ⅷ
Conformity Assessment Procedure:	Article 48 (10), IVDR (EU) 2017/746
STANDARDS APPLIED:	EN ISO 14971:2019 / EN ISO 18113-1:2013 / EN 13612:2002 EN ISO 13485:2016 / EN ISO 18113-2:2013 / EN 62366:2015 EN ISO 23640:2016 / EN ISO 15223-1:2016 / EN 13641:2015 ISO/TR 24971:2020 / ISO 20916:2019 / EN 14820:2004

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR). All supporting documentations are retained under the premises of the manufacturer.

China
Oct 1, 2022
Place, date

Renjiang Li
CEO
Legally binding signature, Function

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

EU DECLARATION OF CONFORMITY

According to Article 17 of Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices

Manufacturer:	Changsha Renji Medical Equipment Co., Ltd. 201, Stage 4, Changsha E Center, No.18 Xiangtai Road, Liuyang Jingkai District, Changsha City, 410300,Hunan Province, China
SRN:	CN-MF-000030318
European Representative:	MedUnion S.L. Carrer de Tapioles, 33, 2-1, 08004, Barcelona, Spain
SRN:	ES-AR-000019366
Product Name:	Polystyrene L-shape Spreader
Product Model:	1pc/pouch, 10pcs/pouch
Intended Use:	Microscope slide is used to culture and analyze cells on a glass microscope slide.

Classification acc. to IVDR Ax. VIII:	Class A , Rule 5 (b) of IVDR Annex Ⅷ		
Conformity Assessment Procedure:	Article 48 (10), IVDR (EU) 2017/746		
STANDARDS APPLIED:	EN ISO 14971:2019	EN ISO 18113-1:2013	EN 13612:2002
	EN ISO 13485:2016	EN ISO 18113-2:2013	EN 62366:2015
	EN ISO 23640:2016	EN ISO 15223-1:2016	EN 13641:2002
	ISO/TR 24971:2020	ISO 20916:2019	EN 14820:2004

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR). All supporting documentations are retained under the premises of the manufacturer.

Oct 1,2022 China — *Place, date*

Renjiang Li — *Legally binding signature, Function*

CHANGSHA RENJI MEDICAL EQUIPMENT CO.,LTD.

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

EU DECLARATION OF CONFORMITY

According to Article 17 of Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices

Manufacturer:	Changsha Renji Medical Equipment Co., Ltd. 201, Stage 4, Changsha E Center, No.18 Xiangtai Road, Liuyang Jingkai District, Changsha City, 410300,Hunan Province, China
SRN:	CN-MF-000030318
European Representative:	MedUnion S.L. Carrer de Tapioles, 33, 2-1, 08004, Barcelona, Spain
SRN:	ES-AR-000019366
Product Name:	Urine Sediment Counting Chamber
Product Model:	10 tests/piece
Intended Use:	Routine urinalysis includes both chemical contents detecting and urinary sediment (formed elements) microscopic examination. Urinary sediment quantitative analyzer is the basic instrument of the standardization detecting of urinary sediment, which will provide the detection of urinary sediment with accuracy, consistent, and safety. It can be easy to operate, and effectively to prevent the contamination with urine specimen for the operator.
Classification acc. to IVDR Ax. VIII:	Class A , Rule 5 (b) of IVDR Annex Ⅷ
Conformity Assessment Procedure:	Article 48 (10), IVDR (EU) 2017/746

STANDARDS APPLIED:	EN ISO 14971:2019	EN ISO 18113-1:2013	EN 13612:2002
	EN ISO 13485:2016	EN ISO 18113-2:2013	EN 62366:2015
	EN ISO 23640:2016	EN ISO 15223-1:2016	EN 13641:2002
	ISO/TR 24971:2020	ISO 20916:2019	EN 14820:2004

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR). All supporting documentations are retained under the premises of the manufacturer.

Oct 1,2022 China

CHANGSHA RENJI MEDICAL EQUIPMENT CO.,LTD.

Renjiang Li

Place, date *Legally binding signature, Function*

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

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Ansă bacteriologică		10µl	
2		Bastonașe de sticlă			
3		Container		nesteril mase fecale 30ml	
4		Container		steril mase fecale 30ml	
5		Container		steril spută 30ml	
6		Cutie Petri		120x120mm	
7		Eprubete		pentru recoltarea sângelui, K3EDTA 0,1ml	
8		Eprubete		cu vacuum pentru recoltarea sângelui, Citrat de sodiu 2,7ml	
9		Eprubete		cu vacuum pentru recoltarea sângelui, VSH 3,6ml	
10		Eprubete		cu vacuum pentru recoltarea sângelui, Activator de coagulare 4,5ml	
11		Spatulă bacteriologică		sterilă forma L	
12		Cameră pentru calcularea sedimentului urinar			

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

Digitally signed by Moraru Grigore
Date: 2023.08.24 10:16:52 EEST
Reason: MoldSign Signature
Location: Moldova