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 **Pari GmbH, Germania:**

- Sistem de inhalare, PARI BOY Classic, 130B1020

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 **25.08.2023** 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	

Digitally signed by Moraru Grigore
Date: 2023.08.25 17:00:16 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 **Pari GmbH, Germania:**

- Sistem de inhalare, PARI BOY Classic, 130B1020

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia:

RA-Manager – Sandu Irina

Semnătura _____

Data ***25.08.2023***

PARI GmbH Spezialisten für effektive Inhalation
P.O. Box 1551 · 82317 Starnberg, GERMANY

To whom it may concern

Contact person:
Jacek Wawrzyczek
Area Manager
Eastern Europe & Middle East
Phone: +49 911 80199404
Fax.: +49 911 80199405
E-Mail:
jacek.wawrzyczek@pari.com

Starnberg, 19th of July, 2023

LETTER OF AUTHORISATION

We, **PARI GmbH**, based in, Moosstrasse 3, 82319 Starnberg, Germany, **assign**

Dita EstFarm SRL, based in Str. Burebista 23, Chisinau, MD - 2032, Moldova,

as **authorized representative** to sell PARI products and participate in tenders in the territory of Republic of Moldova.

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.

This authorisation is valid till 30th of June 2024.

Yours sincerely,

PARI GmbH
Specialists in effective Inhalation

Gildas Bonduelle
Vice President Sales EU

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 011861 0631 Rev. 00

Manufacturer:

PARI GmbH, Spezialisten für effektive Inhalation
Moosstr. 3
82319 Starnberg
GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 011861 0631 Rev. 00

Report No.: 713181777

Valid from: 2021-05-25
Valid until: 2026-05-24

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-05-25

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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 011861 0631 Rev. 00

Classification:	IIa
Device Group:	R060101 - COLD NEBULIZING SYSTEMS
Intended Purpose:	-

Classification:	IIa
Device Group:	Y030399 - RESPIRATORY THERAPY DEVICES - OTHERS
Intended Purpose:	-

The validity of this certificate depends on conditions and/or is limited to the following: - none -

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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ID-Nr. 130-MDR-001-000

EU Declaration of Conformity for Medical Devices

In accordance with Annex IX Chapter I, II (excluding 5 and 6)

of **Medical Device Regulation (EU) 2017/745**

and in accordance with **RoHS Directive 2011/65/EU**
(Restriction of the use of certain hazardous substances in electrical and electronic appliances)

We

PARI GmbH, Spezialisten für effektive Inhalation
SRN (Single Registration Number): DE-MF-000006567

Moosstraße 3
82319 Starnberg
GERMANY

hereby declare under sole responsibility that the medical device

PARI BOY (Type 130)

(Compressor for Inhalation Therapy)

Basis-UDI-DI: 426002043-P130-1000-00FT

Risk Classification according to Regulation (EU) 2017/745, Annex VIII: IIa

complies with the general safety and performance requirements of the

Medical Device Regulation (EU) 2017/745 dated 25th May 2017

and complies with

RoHS Directive 2011/65/EU dated 8th June 2011

Restricted substances referred to in Article 4(1) and maximum concentration values tolerated by weight in homogeneous materials:

- Lead (0.1 %)
- Mercury (0.1 %)
- Cadmium (0.01 %)
- Hexavalent chromium (0.1 %)
- Polybrominated biphenyls (PBB) (0.1 %)
- Polybrominated diphenyl ethers (PBDE) (0.1 %)

On 31st March 2015 the **Delegated Directive (EU) 2015/863** amended the list by following restricted substances:

- Bis(2-Ethylhexyl) phthalate (DEHP): 0.1%
- Benzyl butyl phthalate (BBP): 0.1%
- Dibutyl phthalate (DBP): 0.1%
- Diisobutyl phthalate (DIBP): 0.1%

ID-Nr. 130-MDR-001-000

This Declaration is effective for products placed on the market as of the date of issue and remains valid until a modification is necessitated by a conformity related change (resp. at the latest until the EU-Certificate listed below expires), whereupon a new conformity declaration will be issued.

The applied harmonised standards and common specifications are listed in the Technical Documentation.

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, D-80339 München, Germany,
EU-Certificate: G10 011861 0631 Rev. 00 (Expiry: 24.05.2026)

CE 0123

Starnberg, December 29, 2021

Jürgen Müller
- President -

ID-Nr. 130-MDR-001-000

Attachment

This Declaration of Conformity is valid for the following configurations:

REF No.	Product Name	Annotation
130B1020	PARI BOY Classic	Compressor EU (w/o UK)
130G0015	PARI BOY Rental Set	Set Benelux

END OF DOCUMENT

Nr.	Numărul de catalog (referinţă)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1	130B1020	Sistem de inhalare	PARI BOY	Classic