Anexa nr. 1
La Procedurile administrative pentru notificarea
dispozitivelor medicale care deţin marcajul CE

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 în mun.Chișinău, str. Burebista 23, tel: 022 405 353, e-mail office@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:

Nr.	Denumire	Modelul	Tara	Producător
1	Set de unică folosință pentru sistemul de afereză	Disposable Blood Component Apheresis set, P-2000IG	China	Sichuan Nigale Biotechnology Co., Ltd.

Se anexează următoarele acte:
1. Scrisoarea de autorizare de la producător;
2. Declarația de conformitate CE;
3. Certificat de conformitate CE;
4. Declarația pe proprie răspundere;
5. Lista dispozitivelor medicale supuse modificării.

Digitally signed by Chirtoacă Iurie
Date: 2023.07.14 15:38:20 EEST
Reason: MoldSign Signature
Location: Moldova

CHIRTOACĂ Iurie
Director Semnătura _____

Tabelul de recepționare a notificării

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	

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitivelor Medicale

DECLARATIE PE PROPRIE RĂSPUNDERE

Solicitant Dita EstFarm SRL, cu sediul în mun.Chișinău, str. Burebista 23, tel: 022 405 353, e-mail office@dita.md, declar pe proprie răspundere, cunoscând prevederile art.3521, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea următoarelor dispozitive medicale (Producător – Sichuan Nigale Biotechnology Co., Ltd.):

Nr.	Denumire	Modelul	Tara	Producător
1	Set de unică folosință pentru sistemul de afereză	Disposable Blood Component Apheresis set, P-2000IG	China	Sichuan Nigale Biotechnology Co., Ltd.

Sunt autentice și corespund realității.

CHIRTOACĂ Iurie
Director *Semnătura* _____

LETTER OF AUTHORIZATION

We, **Sichuan Nigale Biotechnology Co., Ltd,** located at No.28 Kuixing Road 641400 Jianyang, Sichuan PEOPLE'S REPUBLIC OF CHINA, as the manufacturer of the following medical devices: disposable plastic blood bags, disposable plasma apheresis set, disposable blood component apheresis set, disposable blood collection and transfusion set, disposable blood bags with in-line leukoreduced filter, plasma separator, blood component separator, blood cell processor, including all the articles mentioned in the Declarations of Conformity attached to this submission, hereby authorize **Dita EstFarm SRL**, located on 23, Burebista Str., Chisinau, MD2032, Republic of Moldova as the exclusive representative, importer and distributor, to prepare and submit applications for the evaluation and registration of the abovementioned medical devices at the Competent authorities on our behalf.

This authorisation shall remain in effect until our notification to the Competent authorities in writing (either by postal mail, e-mail or facsimile transmission) that it is revoked – subject to any conditions imposed by the Competent authorities.

We undertake to provide all the necessary support and assistance to the representative as may be required in relation to any matter involving the above mentioned medical devices.

We agree to provide and assist the competent authorities with any request for information on the above mentioned medical devices.

The authorisation is valid until further notice.

For and on behalf of

General Manager

Nick Liu

Add: Room 901-910, 9/F, Unit 2, Bldg 1, No. 401 Sheng'an Dist., Chengdu, 610041, Sichuan, P. R. China
Fax: +86 28 85122235Street, Hi-Tech.
Tel: +86 28 85122235

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

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

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 067972 0007 Rev. 02

Manufacturer:

Sichuan Nigale Biotechnology Co., Ltd.
No.28 Kuixing Road
641400 Jianyang, Sichuan
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

**Disposable Plastic Blood Bag,Disposable Plasma Apheresis Set,
Disposable Blood Component Apheresis Set,
Disposable Blood Collection and Transfusion Set,
Disposable Blood Bag with In-line Leukoreduced Filter,
Plasma Separator, Blood Component Separator,
Blood Cell Processor**

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. 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:G1 067972 0007 Rev. 02

Report No.: SH19517EXT01

Valid from: 2021-05-25

Valid until: 2024-05-26

Date, 2021-05-25

Christoph Dicks
Head of Certification/Notified Body

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®

File Name: Declaration of conformity File No.: NGL140-CE-18-09/01-00

Declaration of Conformity

1 .Overview

To ensure the products satisfy with MDD/93/42/EEC before releasing declaration of conformity, the company draws up, signs and submits a control procedure to declaration of conformity of products marked CE. The quality department is responsible for drawing up, management representative guarantees the product is in accordance withMDD93/42/EEC MDD93/42/EEC, and the general manager is in charge of signing officially.

2 . Assurance of conformity

Before drawing up the declaration, it is necessary to ensure the product complies with MDD93/42/EEC and confirm to finish rhe following tasks.

2.1Classificationof product

2.2 Validation of certification way

2.3The product has been in accordance with the basic requirements in MDD93/42/EEC Appendix I

2.4he product has been in accordance with the requirements in harmonized standard and related regulations.

2.5The technical files have been drawn up according to MDD/93/42/EEC.

2.6The quality control system of product is according to MDD/93/42/EEC.

2.7The above tasks have notified agency approval

3. The contents of declaration of conformity

Declaration of Conformity

Manufacturer: Sichuan Nigale Biotechnology Co., Ltd.

Address of Manufacturer: NO.28 KuiXing Road 641400 JianYang SiChuan PEOPLE'S REPUBLIC OF CHINA

European representative: Shanghai International Holding corp.Gmbh(Europe)

Address of European representative: **Eiffestrasse 80, 20537 Hamburg, Germany**

Product Name: **Disposable Blood Component Apheresis set**

Model Number:**P-2000、P-2000Ⅰ、P—2000ⅠA、P—2000ⅠB、P—2000ⅠD、P-2000ⅠE、P-2000ⅠF、P-2000ⅠG、P-2000IJ、P-2000IM、P-2000IN、P-2000IP、P-2000IQ、P-2000IR、P-2000IS、P-2000IT、P-2000IV、P-2000IX.**

GMDN Code: 58091

NBOG Code: MD0102

Classification (MDD, Annex IX): **IIb, rule 3**

Conformity Assessment Route: **Annex II.3**

We here with declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for this DoC.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007

Notified Body: **TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany**

NB Identification number: **0123**

(EC) Certificate(s): G1 06 7972 0007 Rev.02

Expire date of the Certificate: **2024-05-26**

Start of CE Marking: **2011-4**

Place, Date of Issue: JianYang SiChuan , 2021-06-07

Signature: Liu NanJian

Name: **LiuNanJian**

Position: **General Manager**