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

Digitally signed by Şarco Alexandru
Date: 2023.11.10 14:43:27 EET
Reason: MoldSign Signature
Location: Moldova

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**