Declaration of Conformity

Manufacturer: Sichuan Nigale Biotechnology Co., Ltd.

Address of Manufacturer: No.28 Kuixing Road 641400 Jianyang，Sichuan, PEOPLE'S REPUBLIC OF CHINA

Address of Facility: 4th F, No.2 Factory Building , Shiyang Industrial Park , No.55, Section 5th, Qingyun Village, Hi-tech. District, 610041 Chengdu，PEOPLE'S REPUBLIC OF CHINA

European representative: Shanghai International Holding Corp. GmbH (Europe)

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

Product Name: Blood Component Separator

Model Number: NGL XCF3000

NBOG Code: MD1101_2

GMDN Code: 16405

Classification: II b , Rule 11

Conformity Assessment Route: Annex II excluding (4)

We herewith 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

Gerneral 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 067972 0007 Rev.02

Expire date of the Certificate: May 26, 2024

Start of CE Marking: May 25, 2021

Place, Date of issue: Chengdu

Signature: Lu Yan

Name : Lu Yan

Position: General Manager of Device Department

Digitally signed by Şarco Alexandru
Date: 2022.11.25 15:50:00 EET
Reason: MoldSign Signature
Location: Moldova