| File Name | Declaration of Conformity of the Plasma Separator | | |
|---|---|---|---|
| File No. | NGL XJC 2000-CEA-03-01 | | |
| Execution Date | 2013-11-9 | | |
| Distributing Departments | Hospital products division general manager | Equipment production and technology director for hospital products divisionr | Equipment technology department of hospital products division |
| | Quality department of hospital products division | E. U. Representative | |
| | | | |

| | Revision No. | Reason and Content | Execution Date |
|---|---|---|---|
| Modified Record | 01 | Modify the related contents ,according to the latest EC certification requirements of Sichuan Nigale Biological Technology Co., Ltd<br>No.1 Modify the "manufacturer and its address"<br>No.2 Modify the"European representative"<br>No.3Modify the "(EC)Certificate(s) code "<br>No.4 Modify the"expire date of the Certificate" | 2014-09-19 |
| | 02 | Modify the related content: according to the requirements of the latest EC certification to modify the following several aspects.<br>No.1 Modify the manufacturer name<br>No.2Modify the (EC)Certificate(s) code<br>No.3Modify general manager signature | 2015-1-11 |
| | 03 | Modify the related content: according to the requirements of the latest EC certification to modify the following several aspects.<br>No.1 Increase the conformity Declaration<br>No.2 Increase the NBOG Code<br>No.3Modify the (EC)Certificate(s) code<br>No.4Modify general manager signature | 2018-1-16 |
| | 04 | Modify the related content: according to the requirements of the latest EC certification to modify the following several aspects.<br>No.1Modify the (EC)Certificate(s) code<br>No.2Modify general manager signature | 2019-6-17 |
| | 05 | Modify the related content:<br>No.1 (EC)Certificate(s) code<br>No.2 delete "Date of issue" | 2019-8-01 |
| | 06 | Modify Name from Feng Ronghua to Lu Yan | 2020-06-10 |

Digitally signed by Şarco Alexandru
Date: 2022.07.25 16:23:31 EEST
Reason: MoldSign Signature
Location: Moldova

| | | | |
|---|---|---|---|
| | 07 | Modify the related content:<br>No.1Modify the NBOG Code<br>No.2Modify the Conformity Assessment Route<br>No.3Modify the Expire date of the Certificate<br>No.4Modify the Start of CE Marking | 2020-10-20 |
| | 08 | Modify the related content:<br>No.1 (EC)Certificate(s) code<br>No.2 Modify the Start of CE Marking<br>No.3 Modify the Expire date of the Certificate | 2021-06-05 |

# Declaration of Conformity of the Plasma Separator

## 1. Overview

To ensure that the *Declaration of Conformity* of the product with CE-marking is under control, that the product is in accordance with requirements of MDD/93/42/EEC before the release of *Declaration of Conformity*. The company established a control procedure for the product with CE-marking to draw up, sign and submit its *Declaration of Conformity*. The quality department is responsible for drawing up, the management representative guarantees the product is in accordance with 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 is complied with MDD93/42/EEC and confirms the completion of the following tasks.

2.1 Classification of products.

2.2 Validation of certification route.

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

2.4 The product has been in accordance with the requirements of harmonized standard and relative regulations.

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

2.6 The quality assurance system of product is in accordance with MDD/93/42/EEC.

2.7 The above tasks have been approved by notified body.

## 3. The Contents of the 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

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:Plasma Separator

Model Number:NGL XJC2000, DigiPla 80, DigiPla 90

NBOG Code:MD1101_2

GMDN Code:16405

Classification(MDD, Annex Ⅸ): Ⅱb , 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: May25, 2021

Place, Date of issue: Chengdu

Signature: Lu Yan

Name : Lu Yan

Position: General Manager of Device Department