



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 division	Equipment technology department of hospital products division
	Quality department of hospital products division	E. U. Representative	
Modified Record	Revision No.	Reason and Content	Execution Date
	01	Modify the related contents according to the latest EC certification requirements of Sichuan Nigale Biological Technology Co., Ltd No.1 Modify the "manufacturer and its address" No.2 Modify the "European representative" No.3 Modify the "(EC)Certificate(s) code" 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. No.1 Modify the manufacturer name No.2 Modify the (EC)Certificate(s) code No.3 Modify 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. No.1 Increase the conformity Declaration No.2 Increase the NBOG Code No.3 Modify the (EC)Certificate(s) code No.4 Modify 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. No.1 Modify the (EC)Certificate(s) code No.2 Modify general manager signature	2019-6-17
	05	Modify the related content: No.1 (EC)Certificate(s) code No.2 delete "Date of issue"	2019-8-01
	06	Modify Name from Feng Ronghua to Lu Yan	2020-06-10

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

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 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

