SYC/JY-CE19-0001 Edition: C/1

< Jiangsu Suyun Medical Materials Co., Ltd >

< Site 1: Jiangsu Suyun Medical Materials Co., Ltd., No.1 Medicine

Lane, Renmin Rd., 222002 Lianyungang, PEOPLE'S REPUBLIC

OF CHINA

Site 2:No.18 Jin Qiao Road, Dapu Industrial Park, 222002 Lianyungang, Jiangsu Province, PEOPLE'S REPUBLIC OF

CHINA >

MEDICAL DEVICE: < Sterile Urine Drainage Bag for single use>

SPECIFICATION: <Child type and adult type >

CLASSIFICATION - ANNEX IX: Class I sterile, Rule 1

MANUFACTURER:

CONFORMITY ASSESSMENT ROUTE: MDD 93/42/EEC Annex V

WE, JIANGSU SUYUN MEDICAL MATERIALS CO., LTD, HERE WITH DECLARE THAT THE STATED MEDICAL DEVICE MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES;

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER, AND THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

TÜV SÜD PRODUCT SERVICE GMBH NOTIFIED BODY:

RIDLERSTR. 65 - 80339 MUNICH, GERMANY

C € ₀₁₂₃ IDENTIFICATION NUMBER

No.G2S 043337 0044 Rev.03 (EC) CERTIFICATE(S):

EXP. DATE: <2024-4-13 >

SIGNATURE:

Shanghai International Holding Corp. GmbH (Europe) EC REP Eiffestrasse, 80, D-20537, Hamburg, Germany Tel: 0086-021-

EUROPEAN REPRESENTATIVE:

65951371, 0049-40-2513175, Fax: 0049-40-255726

START OF CE-MARKING: <2008.12.09>

PLACE, DATE OF DECLARATION: <LIANYUNGANG>, 2021-08-24

POSITION:

GENERAL MANAGER

SYC/JY-CE-83-0001

MANUFACTURER:

< Jiangsu Suyun Medical Materials Co., Ltd >

< Site 1: Jiangsu Suyun Medical Materials Co., Ltd., No.1 Medicine Lane, Renmin Rd., 222002 Lianyungang, PEOPLE'S REPUBLIC OF CHINA

Site 2:No.18 Jin Qiao Road, Dapu Industrial Park, 222002 Lianyungang, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA >

MEDICAL DEVICE:

STERILE LARYNGOLOGICAL SPECULUM FOR SINGLE USE

Edition: B/3

CLASSIFICATION:

Class I Sterile, Rule 5

CONFORMITY ASSESSMENT ROUTE:

MDD 93/42/EEC Annex V

WE, JIANGSU SUYUN MEDICAL MATERIALS CO., LTD, HERE WITH DECLARE THAT THE STATED MEDICAL DEVICE MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER, AND THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH

RIDLERSTR. 65 - 80339 M NCHEN, GERMA II NY

IDENTIFICATION NUMBER:

C € ₀₁₂₃

(EC) CERTIFICATE(S):

G2S 043337 0044 Rev.03

EXP. DATE:

<2024-04-13 >

EC REP

Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse, 80, D-20537, Hamburg, Germany Tel: 0086-021-

65951371, 0049-40-2513175, Fax: 0049-40-255726

START OF CE-MARKING:

EUROPEAN REPRESENTATIVE:

2012.09

PLACE, DATE OF DECLARATION:

<LIANYUNGANG>, 2020-08-24

SIGNATURE:

ZINGJUN ZHANG U

NAME: MR. QINGJUN ZHANG

POSITION:

GENERAL MANAGER

SYC/JY-CE-69-0001

Edition: B/3

MANUFACTURER:

< Jiangsu Suyun Medical Materials Co., Ltd >

< Site 1: Jiangsu Suyun Medical Materials Co., Ltd., No.1 Medicine Lane, Renmin Rd., 222002 Lianyungang, PEOPLE'S REPUBLIC OF CHINA

Site 2:No.18 Jin Qiao Road, Dapu Industrial Park, 222002 Lianyungang, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA >

MEDICAL DEVICE:

Sterile Otolaryngological Set for single use

Large Medium Small-type

CLASSIFICATION - ANNEX IX:

Class I Sterile, Rule 5

CONFORMITY ASSESSMENT ROUTE:

MDD 93/42/EEC Annex V

WE, JIANGSU SUYUN MEDICAL MATERIALS CO., LTD, HERE WITH DECLARE THAT THE STATED MEDICAL DEVICE MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER, AND THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR. 65 - 80339 M NCHEN, GERMA II NY

IDENTIFICATION NUMBER

C € ₀₁₂₃

(EC) CERTIFICATE(S):

G2S 043337 0044 Rev.03

EXP. DATE:

<2024-04-13 >

EC REP

Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse, 80, D-20537, Hamburg, Germany Tel: 0086-021-65951371, 0049-40-2513175, Fax: 0049-40-255726

START OF CE-MARKING:

EUROPEAN REPRESENTATIVE:

2009.04

PLACE, DATE OF DECLARATION:

<LIANYUNGANG>, 2020-08-24

SIGNATURE:

NAME: MR. QINGJUN ZHANG

POSITION:

GENERAL MANAGER

Ref: EN ISO/IEC 17050-1 revision date: June 2009

SYC/JY-CE28-0001

Edition:D/1

MANUFACTURER:

< Jiangsu Suyun Medical Materials Co., Ltd >

< Site 1: Jiangsu Suyun Medical Materials Co., Ltd., No.1 Medicine Lane, Renmin Rd., 222002 Lianyungang, PEOPLE'S REPUBLIC OF CHINA

Site 2:No.18 Jin Qiao Road, Dapu Industrial Park, 222002 Lianyungang, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA >

MEDICAL DEVICE:

STERILE GYNAECOLOGICAL COLLECTORS FOR SINGLE USE

IA、IA-2、IA-3、IB、IC IIA、IIB-1、IIB-2、IIB-3

IIIA、IIIA-2、IIIB、IIIB-2、IIIB-3、IIIB-4、IIIB-M1、

IIIB-M2、IIIB-M3、IIIC、IIID、IIID-2

CLASSIFICATION - ANNEX IX:

CLASS I STERILE, RULE 5

CONFORMITY ASSESSMENT ROUTE:

MDD 93/42/EEC ANNEX V

WE, JIANGSU SUYUN MEDICAL MATERIALS CO., LTD, HERE WITH DECLARE THAT THE STATED MEDICAL DEVICE MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER, AND THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH

RIDLERSTR. 65 - 80339 M NCHEN, GERMA II NY

IDENTIFICATION NUMBER

C € ₀₁₂₃

(EC) CERTIFICATE(S):

G2S 043337 0044 Rev.03

EXP. DATE:

<2024-04-13 >

EC REP

EUROPEAN REPRESENTATIVE:

Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse, 80, D-20537, Hamburg, Germany Tel: 0086-021-

65951371, 0049-40-2513175, Fax: 0049-40-255726

START OF CE-MARKING:

2006.02

PLACE, DATE OF DECLARATION:

<LIANYUNGANG>, 2020-08-24

SIGNATURE:

QINGJUN ZHANG

NAME: MR. QINGJUN ZHANG

POSITION:

GENERAL MANAGER

Ref: EN ISO/IEC 17050-1 revision date: June 2009