

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

SYC/JY-CE-28-0001

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 Urinary Catheter for Single Use (Nelaton Catheter, Foley
Catheter and Silicone Catheter)

SPECIFICATION:

F511010, F511012, F511014, F511016, F511018, F510008,
F510010, F510012, F510014, F510016, F510018, S512212,
S512214, S512216, S512218, S512220, S512222, S512224, S512318,
S512320, S512322, S512324,
513216, 513218, 513220, 513222, 513224

CLASSIFICATION - ANNEX IX:

Class IIa Rule 5

CONFORMITY ASSESSMENT ROUTE:

MDD 93/42/EEC Annex II excluding (4)

WE, THE MANUFACTURER, 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 MÜNCHEN, GERMANY**

IDENTIFICATION NUMBER

CE 0123

(EC) CERTIFICATE(S):

G1 043337 0047 Rev.01

EXP. DATE:

2022-06-13



EUROPEAN REPRESENTATIVE:

Shanghai International Holding Corp. GmbH (Europe)

Eiffestr.80, D-20537, Hamburg, Germany Tel: 0086-021-
65951371, 0049-40-2513175, Fax: 0049-40-255726

START OF CE-MARKING:

2005.04.10

PLACE, DATE OF DECLARATION:

LIANYUNGANG, 2019-09-19

SIGNATURE:

NAME: MR. QIN HONGPING

POSITION:

PRESIDENT