

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



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 Suction Catheter for single use

CODE:

F520006, F520008, F520010, F520012, F520014, F520016, F520018, F520020

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:

2022-6-13



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:

2008.11.11

PLACE, DATE OF DECLARATION:

LIANYUNGANG, 2019-9-19

SIGNATURE:

NAME: MR. QIN HONGPING
POSITION:
PRESIDENT

江苏苏云医疗器材有限公司
JIANGSU SUYUN MEDICAL MATERIALS CO., LTD.

秦宏平