

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

SYC/JY-CE10-0001

Edition: B/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:

<Without balloons type、 with a balloon and double funnels type、 with a balloon and triple funnels type >

CLASSIFICATION - ANNEX IX:

Class IIa, Rule 5

CONFORMITY ASSESSMENT ROUTE:

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

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 MUNICH, GERMANY**

IDENTIFICATION NUMBER

CE 0123

(EC) CERTIFICATE(S):

No.G1 043337 0047 Rev.01

EXP. DATE:

<2022-6-13 >



EUROPEAN REPRESENTATIVE:

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START OF CE-MARKING:

<2010.08.25>

PLACE, DATE OF DECLARATION:

<LIANYUNGANG>, 2021-1-10

SIGNATURE:

NAME: MR. QINGJUN ZHANG
POSITION: GENERAL MANAGER

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

秦宏平