

# DECLARATION OF CONFORMITY MEDICAL DEVICE REGULATION 2017/745 CONCERNING MEDICAL DEVICES

**SYC/JY-CE28-0001**

**Edition: A/0**



**MANUFACTURER:**

NAME: JIANGSU SUYUN MEDICAL MATERIALS CO., LTD.  
ADDRESS: NO.18 JIN QIAO ROAD, DAPU INDUSTRIAL PARK,  
LIANYUNGANG, JIANGSU PROVINCE, PEOPLE'S REPUBLIC OF CHINA  
POSTAL CODE:222002  
SRN:CN-MF-000021132

**MEDICAL DEVICE:**

NAME: STERILE GYNAECOLOGICAL COLLECTORS FOR SINGLE USE  
TYPE : IA,IA-2,IA-3,IB,IC,IC-1,IC-2,IC-3,IC-4,IC-5,IC-6,IC-7,IC-8,IC-9,IC-10,IC-11,  
IC-12,IC-13,IC-14,IC-15,IC-16,IC-17,IC-18,IIA-1,IIA-2,IIA-3,IIA-4,IIA-5,IIA-6,IIB-1,IIB-2,IIB-3,IIIA,  
IIIA-2,IIIB,IIB-2,IIIB-3,IIIB-4,IIIB-M1,IIIB-M2,IIIB-M3,IIIC,IIID,IIID-2,IIID-3,IIID-4,IIID-5,ID  
CODE:420211,420222,477701,420301,420311,420411,420414,425002  
INTENDED PURPOSE: THE MAIN CLINICAL USAGE IS TO SAMPLE FOR GYNECOLOGY AND VENEREAL DISEASE.  
BASIC UDI-DI:69332982028  
CLASSIFICATION - ANNEX VIII: RULE 5: CLASS I, STERILE  
CONFORMITY ASSESSMENT ROUTE: ANNEX IX(CHAPTER I +III)

WE, JIANGSU SUYUN MEDICAL MATERIALS CO.,LTD., HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE MEDICAL DEVICE REGULATION RUGULATION 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017.WE STATED THAT THE EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF OUR COMPANY.

STANDARDS APPLIED: EN ISO 13485:2016/A11:2021, EN ISO 14971:2019/A11:2021, EN ISO 11135:2014/A1:2019, EN ISO 11607-1:2020/A1:2023,EN ISO 11607-2:2020/A1:2023, EN ISO 10993-1:2020, EN1422:2014, EN ISO 11737-1:2018/A1:2021, EN ISO 11737-2:2020, MEDDEV2.7.1 Rev 4, EN ISO15223-1:2021.

**NOTIFIED BODY:**

TÜV SÜD PRODUCT SERVICE GMBH  
RIDLERSTRASSE 65, 80339 MUNICH, GERMANY

**IDENTIFICATION NUMBER**

**CE** 0123

**(EC) CERTIFICATE(S):**

**No. G11 066729 0008 Rev. 00**



**EUROPEAN REPRESENTATIVE:**

Shanghai International Holding Corp. GmbH (Europe)  
Eiffestraße 80, 20537 Hamburg, Germany  
Tel: 0049-40-255726

**PLACE, DATE OF DECLARATION:**

LIANYUNGANG, JIANGSU DATE: 2025-05-22

**SIGNATURE:**

江苏苏云医疗器械有限公司  
NAME: ZHANG QINGJUN  
POSITION: RESPONSIBLE SENIOR EXECUTIVE OF MANUFACTURER

张宏平