

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

**SYC/JY-CE28-0002**

**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: GYNAECOLOGICAL COLLECTORS FOR SINGLE USE  
TYPE : IIIB-M2 CODE: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  
CONFORMITY ASSESSMENT ROUTE: ANNEX IX(CHAPTER I +III)*

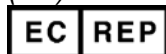
WE, JIANGSU SUYUN MEDICAL MATERIALS CO.,LTD., HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE MEDICAL DEVICE REGULATION RUGULATION 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017.WE STATED THAT THE EU DECLARATION OF CONFORMITY IS ISSUED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

STANDARDS APPLIED: EN ISO 13485:2016/A11:2021, EN ISO 14971:2019/A11:2021, EN ISO 10993-1:2020,EN ISO 11737-1:2018/A1:2021, MEDDEV2.7.1 REV 4, EN ISO15223-1:2021.

*IDENTIFICATION NUMBER*



*(EC) CERTIFICATE(S):*



EUROPEAN REPRESENTATIVE:

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

PLACE, DATE OF DECLARATION:

LIANYUNGANG, JIANGSU DATE: 2025-03-19

SIGNATURE:

NAME: ZHANG QINGJUN

POSITION: RESPONSIBLE SENIOR EXECUTIVE OF MANUFACTURER