

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 : IC, IC-9 SUYUN CODE:420211,420222 GIMA CODE: 29733,29734

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 II, 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 SRN:DE-AR-000000001

PLACE, DATE OF DECLARATION:

LIANYUNGANG, JIANGSU DATE: 2025-03-19

SIGNATURE:

NAME: ZHANG QINGJUN

POSITION: RESPONSIBLE SENIOR EXECUTIVE OF MANUFACTURER

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

张宏平