

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

SYC/JY-CE57-0001

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 GYNECOLOGICAL KIT FOR SINGLE USE
TYPE: MO-1,MO-2,MO-3,ME,AU,PK-1,PK-2,IT,AS No.1,BS No.2,D2S No.3,
E1S No.4,F1S No.5,AM No.6,BM No.7,D2M No.8,E1M No.9,F1M No.10,AL No.11,BL No.12,
D2L No.13,E1L No.14,F1L No.15,S No.16,M No.17,L No.18,NO.1-1,NO.1-2,NO.1-3,NO.7-1,
NO.7-2,NO.7-3,NO.7-4,<NO.2-1,NO.2-2,NO.2-3,,NO.2-4,NO.2-5,NO.2-6,NO.3-1,NO.3-2,NO.3-3,
NO.3-4,NO.3-5,NO.3-6,NO.3-7,NO.3-8,NO.4-1,NO.4-2,NO.5-1,NO.5-2,NO.6-1,NO.6-2,NO.8-1,
NO.8-2,NO.8-3,NO.8-4,NO.9-1,NO.9-2,NO.10-1,NO.10-2,NO.10-3,NO.10-4,NO.10-5,NO.10-6,
NO.10-7,NO.10-8,NO.11-1,NO.11-2,NO.12-1,NO.12-2,NO.13-1,NO.13-2,NO.14-1,NO.14-2,
NO.14-3,NO.14-4,NO.14-5>-<S,M,L>.

CODE: 499901

INTENDED PURPOSE: STERILE GYNECOLOGICAL KIT FOR SINGLE USE IS INTENDS TO USE FOR GYNECOLOGICAL EXAMINATION AND SAMPLING.

BASIC UDI-DI:69332982057

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:

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

秦宏平