

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

SYC/JY-CE04-0001

Edition: A/0



MANUFACTURER: NAME: JIANGSU SUYUN MEDICAL MATERIALS CO., LTD.

SRN: CN-MF-000021132

ADDRESS: NO.18 JIN QIAO ROAD, DAPU INDUSTRIAL PARK,
222002 LIANYUNGANG, JIANGSU PROVINCE,
PEOPLE'S REPUBLIC OF CHINA
POSTAL CODE: 222002

MEDICAL DEVICE: NAME: STERILE VAGINAL SPECULUM FOR SINGLE USE

TYPE AND / OR MODEL: <ES-S, ES-M, ES-L, MIDDLE SCREW-XS, MIDDLE SCREW-S, MIDDLE SCREW-M, MIDDLE SCREW-MEDIUM LONG, MIDDLE SCREW-L, MIDDLE SCREW-MIX, SIDE SCREW-XS, SIDE SCREW-S, SIDE SCREW-M, SIDE SCREW-L, SIDE SCREW-MIX, CENTRAL PIN-XS, CENTRAL PIN-S, CENTRAL PIN-M, CENTRAL PIN-M2, CENTRAL PIN-L, CENTRAL PIN-MIX, KZQ07-S, KZQ07-M, KZQ07-L, KZQ08-S, KZQ08-M, KZQ08-L, KZQ08-MIX, KZQ09-S, KZQ09-M, KZQ09-L, WITH SMOKE TUBE-S, WITH SMOKE TUBE-M, WITH SMOKE TUBE-L>

CODE: 410220, 410228, 410233, 4102MIX, 4106MIX, 4108MIX, 4101MIX

INTENDED PURPOSE: THE MAIN CLINICAL USAGE IS TO SAMPLE FOR GYNECOLOGY AND VENEREAL DISEASE.

BASIC UDI-DI: 69332982004

CLASSIFICATION - ANNEX VIII:

CLASS I STERILE, RULE 5

CONFORMITY ASSESSMENT ROUTE: ANNEX IX (CHAPTER I, III) + ANNEX IX (SECTION 4)

WE, JIANGSU SUYUN MEDICAL MATERIALS CO., LTD., HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE MEDICAL DEVICE REGULATION REGULATION 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.

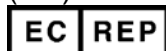
STANDARDS APPLIED: EN ISO 13485:2016/A11:2021, EN ISO 14971:2019/A11:2021, EN ISO 11135:2014/A1:2019, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 10993-1:2020, EN 1422:2014, EN ISO 11737-1:2018/A1:2021, EN ISO 11737-2:2020, MEDDEV 2.7.1 REV 4, EN ISO 15223-1:2021

NOTIFIED BODY:

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

IDENTIFICATION NUMBER

(EC) CERTIFICATE(S):



EUROPEAN REPRESENTATIVE:

CE 0123
No. G11 066729 0008 Rev. 00

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

PLACE, DATE OF DECLARATION:

LIANYUNGANG, JIANGSU

DATE: 2024-03-30

SIGNATURE:

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

NAME: ZHANG QINGJUN
POSITION: GENERAL MANAGER