

DECLARATION OF CONFORMITY

MEDICAL DEVICE REGULATION 2017/745

CONCERNING MEDICAL DEVICES

SYC/JY-CE12-0001

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: NON STERILE APPLICATOR WITH COTTON TIP

PRODUCT CODE: 724205, 724210

BASIC UDI-DI: 69332982066

INTENDED PURPOSE: NON STERILE APPLICATOR WITH COTTON TIP IS INTENDED FOR THE SAMPLER OF GYNAECOLOGY.

CLASSIFICATION - ANNEX VIII: CLASS I, RULE 1

CONFORMITY ASSESSMENT ROUTE: ANNEX II + ANNEX 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 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 20417:2021, EN ISO 15223-1:2021, MEDDEV 2.7.1:2016,



EUROPEAN REPRESENTATIVE:

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SRN: DE-AR-000000001

PLACE, DATE OF DECLARATION:

LIANYUNGANG, JIANGSU

DATE: 2023-6-9

SIGNATURE:

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

NAME: ZHANG QINGJUN
POSITION: GENERAL MANAGER