

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

SYC/JY-CE73-0001

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: MEDICAL TRANSPORT SWAB
TYPE: I-1,I-2,I-3,I-4,I-5,I-6,II-1,II-2,II-3,II-4,II-5,II-6,II-7,II-8,II-9,II-10,II-11,II-12.
CODE: 425101, 425102
INTENDED PURPOSE: TRANSPORT SWAB INTENDED TO USE FOR GYNECOLOGICAL DISEASE OR ENT LESIONS
SAMPLING.
BASIC UDI-DI:69332982073
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



(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