

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

**SYC/JY-CE33-0001**

**Edition:A/0**



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

SRN:CN-MF-000021132

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222002LIANYUNGANG,JIANGSU PROVINCE,  
PEOPLE'S REPUBLIC OF CHINA  
POSTAL CODE:222002

MEDICAL DEVICE:

NAME: *STERILE PROCTOSCOPE FOR SINGLE USE*

TYPE: *I, II, III, IV*

SIZE:SMALL(14#) CODE 723101, MEDIUM(22#) CODE 723102, LARGE(26#) CODE 723103

*INTENDED PURPOSE: STERILE PROCTOSCOPE FOR SINGLE USE IS MAINLY APPLIED TO INSPECTION AND ANAL LESION SURGERY.*

BASIC UDI-DI:69332982033

CLASSIFICATION - ANNEX VIII: CLASS IIA, RULE 5

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 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 11138-2:2017, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022,EN ISO10993-1:2020,EN ISO10993-5:2009, EN ISO10993-10:2013, EN ISO 10993-7:2008/A1:2022, EN ISO15223-1:2021, EN1422:2014, EN ISO 11737-1:2018/A1:2021, EN ISO 11737-2:2020, MEDDEV-2.7.1 REV4 :2016.**

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH  
RIDLERSTR 65, 80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER **CE** 0123

(EC) CERTIFICATE(S): G10 066729 0005 REV.00



EUROPEAN REPRESENTATIVE:

**Shanghai International Holding Corp. GmbH (Europe)**  
**Eiffestrasse, 80, 20537, Hamburg, Germany Tel: 00489-40-**  
**2513175, Fax: 0049-40-255726**  
**SRN:DE-AR-000000001**

PLACE, DATE OF DECLARATION:

LIANYUNGANG, JIANGSU DATE: 2023-6-25

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  
**秦宏平**