

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

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

MEDICAL DEVICE:

NAME: *STERILE PROCTOSCOPE FOR SINGLE USE*

CODE: 723111 (SMALL SIZE) 723112 (MEDIUM SIZE) 723113 (LARGE SIZE)

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 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 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, MEDDEV2.7.1 :2016.**

NOTIFIED BODY:

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

IDENTIFICATION NUMBER  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

PLACE, DATE OF DECLARATION:

LIANYUNGANG, JIANGSU DATE: 2023-03-09

SIGNATURE:



NAME: ZHANG QINGJUN

POSITION: GENERAL MANAGER