

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

SYC/JY-CE11-0001

Edition: A/1



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

SRN: CN-MF-000021132

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

MEDICAL DEVICE:

NAME: *STERILE RECTAL CATHETER FOR SINGLE USE*

TYPE AND / OR MODEL: 6.0mm(18Fr/CH), 6.7mm(20Fr/CH), 7.3mm(22Fr/CH), 8.0mm(24Fr/CH), 8.3mm(25Fr/CH), 8.7mm(26Fr/CH), 9.3mm (28Fr/CH), 10.0mm(30Fr/CH), 10.7mm(32Fr/CH), 11.3mm (34Fr/CH)

CODE: F530118, F530120, F530122, F530124, F530126, F530128, F530130, F530132, F530134

INTENDED PURPOSE: *PATIENTS WHO REQUIRE RECTAL CLEANING.*

BASIC UDI-DI: 69332982011

CLASSIFICATION - ANNEX VIII:

CLASS I, RULE 5, 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 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/A1:2023, EN ISO 11607-2:2020/A1:2023, EN ISO 10993-1:2020, EN 1422:2014, EN ISO 15223-1:2021, ISO 11737-1:2018/A1:2021, MEDDEV 2.7.1: REV 4, EN 12439:1998.**

NOTIFIED BODY:

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

IDENTIFICATION NUMBER

(EC) CERTIFICATE(S):

CE 0123

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: 2024-3-30

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