

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: STERILE SUCTION CATHETER FOR SINGLE USE

TYPE AND/OR MODEL: < (I , II , III , IV , V , VI , VII , VIII , IX , X , XI , XII) - 1.33MM (4FR/CH) ,
1.5MM (4.5FR/CH) , 1.67MM (5FR/CH) , 2.0MM (6FR/CH) , 2.1MM (6.5FR/CH) , 2.33MM
(7FR/CH) , 2.5MM (7.5FR/CH) , 2.67MM (8FR/CH) , 3.0MM (9FR/CH) , 3.33MM (10FR/CH) ,
4.0MM (12FR/CH) , 4.67MM (14FR/CH) , 5.0MM (15FR/CH) , 5.33MM (16FR/CH) , 6.0MM
(18FR/CH) , 6.67MM (20FR/CH) , 7.33MM (22FR/CH) >

CODE: F520006, F520008, F520010, F520012, F520014, F520016, F520018, F520020

INTENDED PURPOSE: STERILE SUCTION CATHETER FOR SINGLE USE IS INTENDED FOR USE IN SUCTION OF THE
RESPIRATORY.

BASIC UDI-DI: 69332982012

CLASSIFICATION - ANNEX VIII: CLASS IIA, RULE 5

CONFORMITY ASSESSMENT ROUTE: ANNEX IX (CHAPTER I , III) + ANNEX IX (SECTION 4)

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 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 10993-
1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN 556-1:2001/AC:2006,
EN 1041:2008+A1:2013, EN ISO 15223-1:2021, EN ISO 10993-7:2008/A1:2022, EN 1422:2014, ISO
11737-1:2018/A1:2021, MEDDEV-2.7.1 REV4: 2016, EN ISO 8836:2014.

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTRASSE 65, 80339 MUNICH, GERMANY

IDENTIFICATION NUMBER
(EC) CERTIFICATE(S): No. 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:

NAME: ZHANG QINGJUN
POSITION: GENERAL MANAGER

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