

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.18JIN 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) >

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 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/A11:2022, EN ISO 11607-2:2020/A11:2022, 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, EN ISO 8836:2014.

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

IDENTIFICATION NUMBER

CE 0123

(EC) CERTIFICATE(S): No. G10 066729 0005 Rev.00

EC REP

EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse, 80, 20537, Hamburg, Germany Tel: 0049-40-255726

PLACE, DATE OF DECLARATION:

LIANYUNGANG, JIANGSU

DATE: 2025-05-23

SIGNATURE:

NAME: ZHANG QINGJUN

POSITION: GENERAL MANAGER

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ANNEX I

Product Corresponding List

No	Suyun Ref. No.	Fahl Ref. No.	Product Name	GMDN Code	Sterility State	Related Product Standard	Device Risk Rule
1	5202-FS10 T	68630-10	TRACHFLOW® SUCTION CATHETER Soft Metric S,30 cm, CH 10	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
2	5202-FS12 T	68630-12	TRACHFLOW® SUCTION CATHETER Soft Metric S,30 cm, CH 12	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
3	5202-FS14 T	68630-14	TRACHFLOW® SUCTION CATHETER Soft Metric S,30 cm, CH 14	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
4	5202-FS16 T	68630-16	TRACHFLOW® SUCTION CATHETER Soft Metric S,30 cm, CH 16	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
5	5200-FS06 T	68100-06	TRACHEOSTOMA SUCTION CATHETER Soft Metric S, 30 cm, CH 6	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
6	5200-FS08 T	68100-08	TRACHEOSTOMA SUCTION CATHETER Soft Metric S, 30 cm CH 8	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
7	5200-FS10 T	68100-10	TRACHEOSTOMA SUCTION CATHETER Soft Metric S, 30 cm, CH 10	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
8	5200-FS12 T	68100-12	TRACHEOSTOMA SUCTION CATHETER Soft Metric S, 30 cm CH 12	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
9	5200-FS14 T	68100-14	TRACHEOSTOMA SUCTION CATHETER Soft Metric S, 30 cm, CH 14	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
10	5200-FS16 T	68100-16	TRACHEOSTOMA SUCTION CATHETER Soft Metric S, 30 cm, CH 16	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
11	5200-FS18 T	68100-18	TRACHEOSTOMA SUCTION CATHETER Soft Metric S, 30 cm CH 18	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5

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No	Suyun Ref. No.	Fahl Ref. No.	Product Name	GMDN Code	Sterility State	Related Product Standard	Device Risk Rule
12	5202-FL08 T	68730-08	TRACHFLOW® SUCTION CATHETER Soft Metric L, 50 cm, CH 8	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
13	5202-FL10 T	68730-10	TRACHFLOW® SUCTION CATHETER Soft Metric L, 50 cm, CH 10	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
14	5202-FL12 T	68730-12	TRACHFLOW® SUCTION CATHETER Soft Metric L, 50 cm, CH 12	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
15	5202-FL14 T	68730-14	TRACHFLOW® SUCTION CATHETER Soft Metric L, 50 cm, CH 14	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
16	5202-FL16 T	68730-16	TRACHFLOW® SUCTION CATHETER Soft Metric L, 50 cm, CH 16	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
17	5200-FL06 T	68000-06	TRACHEOSTOMA SUCTION CATHETER Soft Metric L, 50 cm CH 6	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
18	5200-FL08 T	68000-08	TRACHEOSTOMA SUCTION CATHETER Soft Metric L, 50 cm CH 8	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
19	5200-FL10 T	68000-10	TRACHEOSTOMA SUCTION CATHETER Soft Metric L, 50 cm CH 10	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
20	5200-FL12 T	68000-12	TRACHEOSTOMA SUCTION CATHETER Soft Metric L, 50 cm CH 12	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
21	5200-FL14 T	68000-14	TRACHEOSTOMA SUCTION CATHETER Soft Metric L, 50 cm CH 14	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
22	5200-FL16 T	68000-16	TRACHEOSTOMA SUCTION CATHETER Soft Metric L, 50 cm CH 16	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
23	5200-FL18 T	68000-18	TRACHEOSTOMA SUCTION CATHETER Soft Metric L, 50 cm CH 18	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5