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,
222002LIANYUNGANG,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（6.5 FR/CH）、2.33MM（7FR/CH）、2.5MM（7.5FR/CH）、2.67MM（8FR/CH）、3.0MM（9 FR/CH）、3.33MM（10FR/CH）、4.0MM（12FR/CH）、4.67MM（14FR/CH）、5.0MM（15 FR/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 8836:2020.**

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

DENTIFICATION 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: 2026-03-24*

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	TRACHFLOW⑧ 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	TRACHFLOW⑧ 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	TRACHFLOW⑧ 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	TRACHFLOW⑧ 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	elated 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

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24	5200-FXS06	68200-06	TRACHEOSTOMA SUCTION CATHETER Soft Metric XS, 15 cm CH 6	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
25	5200-FXS08	68200-08	TRACHEOSTOMA SUCTION CATHETER Soft Metric XS, 15 cm CH 8	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
26	5200-FXS10	68200-10	TRACHEOSTOMA SUCTION CATHETER Soft Metric XS, 15 cm CH 10	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
27	5200-FXS12	68200-12	TRACHEOSTOMA SUCTION CATHETER Soft Metric XS, 15 cm CH 12	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
28	5200-FXS14	68200-14	TRACHEOSTOMA SUCTION CATHETER Soft Metric XS, 15 cm CH 14	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
29	5200-FXS16	68200-16	TRACHEOSTOMA SUCTION CATHETER Soft Metric XS, 15 cm CH 16	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
30	5240-FL08	68050-08	TRACHEOSTOMA SUCTION CATHETER Soft metric L Vakon connector, 50 cm CH 8	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
31	5240-FL10	68050-10	TRACHEOSTOMA SUCTION CATHETER Soft metric L Vakon connector, 50 cm CH 10	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
32	5240-FL12	68050-12	TRACHEOSTOMA SUCTION CATHETER Soft metric L Vakon connector, 50 cm CH 12	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
33	5240-FL14	68050-14	TRACHEOSTOMA SUCTION CATHETER Soft metric L Vakon connector, 50 cm CH 14	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
34	5240-FL16	68050-16	TRACHEOSTOMA SUCTION CATHETER Soft metric L Vakon connector, 50 cm CH 16	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5
35	5240-FL18	68050-18	TRACHEOSTOMA SUCTION CATHETER Soft metric L Vakon connector, 50 cm CH 18	34923	Sterile	EN ISO 8836:2020	Class IIa Rule 5