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

SYC/JY-CE10-0001 **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 URINARY CATHETER FOR SINGLE USE(NELATON CATHETER, FOLEY CATHETER AND SILICONE CATHETER)*

TYPE AND / OR MODEL: STERILE URINARY CATHETER FOR SINGLE USE(NELATON CATHETER)
TYPE: PAEDIATRIC MALE,PAEDIATRIC FEMALE,MALE,FEMALE
CODE:F511008,F511010,F511012,F511014,F511016,F511018,F511020,F510006,F510008,F510010, F510012,F510014,F510016,F510018
STERILE URINARY CATHETER FOR SINGLE USE(FOLEY CATHETER AND SILICONE CATHETER)
TYPE:1-WAY,2-WAY,3-WAY
CODE:H512210,H512212,H512214,H512216,H512218,H512220,H512222,H512224,H512226, H512318,H512320, H512322, H512324, 513212,513214,513216,513218,513220,513222,513224

INTENDED PURPOSE：FOR TEMPORARY EMICTION BY INSERTING IT TO BLADDER THROUGH URETHRA WHEN PATIENTS CAN NOT MICTURATE BY THEMSELVES.

BASIC UDI-DI：69332982010

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 11138-2:2017, 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 10993-6:2016, EN ISO 10993-7:2008/A1:2022, EN ISO 10993-10:2013, EN 556-1:2001/AC:2006, EN ISO 15223-1:2021, EN 1422:2014, EN ISO 11737-1:2018/A1:2021, EN ISO 11737-2:2020, MEDDEV-2.7.1REV4:2016 , EN 62366-1:2015, EN ISO 20696:2018.**

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, 80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER: CE 0123

(EC) CERTIFICATE(S): G10 066729 0005 REV.00

EC REP

EUROPEAN REPRESENTATIVE:***Shanghai International Holding Corp. GmbH (Europe) Eiffestraße, 80,20537, Hamburg, Germany Tel: 0049-40-2513175，Fax: 0049-40-255726 SRN:DE-AR-000000001***

PLACE, DATE OF DECLARATION: LIANYUNGANG, JIANGSU *DATE: 2024-2-28*

SIGNATURE:

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

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NAME: ZHANG QINGJUN
POSITION: GENERAL MANAGER