





# Certificate

No. Q5 066729 0001 Rev. 02

**Applied Standard(s):** ISO 13485:2016  
 (EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
 Medical devices - Quality management systems - Requirements for regulatory purposes

**Facility(ies):** **Jiangsu Suyun Medical Materials Co., Ltd.**  
 No.18 Jin Qiao Road, Dapu Industrial Park, 222002 Lianyungang, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Design and development, production and sales of Sterile /Non-sterile Non-active Medical devices (For detailed information see attachment).

**Jiangsu Suyun Medical Materials Co., Ltd.**  
 No.1 Medicine Lane, Renmin Rd., 222002 Lianyungang, PEOPLE'S REPUBLIC OF CHINA

Production of Sterile /Non-sterile Non-active Medical devices (For detailed information see attachment).

Attachment: Sterile Infusion Sets for Single Use, Sterile Transfusion Sets for Single Use, Sterile Syringe for Single Use, Sterile Vaginal Speculum for Single Use, Sterile Urinary Catheter for Single Use (Nelaton Catheter, Foley Catheter and Silicone Catheter), Sterile Gynaecological Collectors for Single Use, Sterile Rectal Catheter for Single Use, Sterile Scalp Vein Sets for Single Use, Sterile Suction Catheter for Single Use, Sterile Blood Collection Needle for Single Use, Sterile Arterial Venous Fistula Needle for Single Use, Sterile Nasal Oxygen Cannula for Single Use, Sterile Proctoscope for Single Use, Laryngeal Mask Airway, Sterile Feeding Catheter for Single Use, Sterile Endotracheal Tube for Single Use, Sterile Insulin Syringe for Single Use, Sterile Stomach Tube with Guide Wire for Single Use, Sterile Stomach Tube for Single Use (Nasogastric Tube, Levin Tube), Sterile Duodenal Tube for Single Use, Sterile Nasal Speculum for Single Use, Sterile Urine Drainage Bag for Single Use, Sterile Feeding Tube for Single Use, Sterile Specimen Container for Single Use, Sterile Applicator with Cotton Tip, Sterile Tongue Depressor, Sterile Otolaryngological Set for Single Use, Trial Lenses Sets, Disposable Curettes, Sterile Gynecological Kit for Single Use, Medical Transport Swab, Heat and Moisture Exchange (Artificial Nose), Sterile Catheter Tip Syringe for Single Use, Intrauterine Insemination Catheter (IUI Cannula), Disposable Uterine Sound (Hysterometers), Sterile Hypodermic Needle for Single Use, Sterile Extension Tube for Single Use, Medical Disposable Bibs, Medical I.D. Bracelet, Sterile Laryngological Speculum for Single use, Sterile Umbilical Cord Clamp for Single Use, Sterile Dental Injection Needles for Single Use, Sterile Amniohook for Single Use, Sterile Intravascular Catheters for Single Use (I.V. Cannula), Suction catheter Kit, Sterile Incision Retractor for Single Use, Light-resistant Infusion Sets for Single Use, Ostomy bags and accessories, Vacuum Blood Collection Tubes, Medical Alcohol Pads, Forceps, Ear funnel, Disposable Circumcision Stapler, Sterile Holder Accessories for Single Use (Fastener, Arm Drape).

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Product Service

# 认证证书

证书号. Q5 066729 0001 Rev. 02

证书持有者 :

江苏苏云医疗器材有限公司

中华人民共和国江苏省连云港大浦工业园金桥路18号 222002

认证标志 :



认证范围 :

设计和开发, 生产, 销售: 无菌/非无菌无源医疗器械  
(详细信息见附件)

认证机构TÜV SÜD产品服务有限公司证明上述公司已经建立并运行了满足所列标准要求的质量管理体系。

TÜV 南德集团检测及认证规则所有适用要求也须得到遵守。详情及证书有效期请见

[www.tuvsud.com/ps-cert?q=cert:Q5 066729 0001 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5 066729 0001 Rev. 02)

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Christoph Dicks

Head of Certification/Notified Body

