

# Certificate

No. Q5 041808 0057 Rev. 05

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** Shanghai Kindly Enterprise Development Group Co., Ltd.  
No 658 Gaochao Road, 201803 Shanghai, PEOPLE'S REPUBLIC  
OF CHINA

Design, Development, Production and Distribution of Sterile 'Infusion Sets, Scalp Vein Sets, Syringes, Transfusion Sets, Infusion Sets with Burette, Urinal Bags, Syringes for insulin, Medical Tubes, Oxygen Cannula, Feeding Tube, Suction Catheter, Rectal Tube, Urethral Catheters, Extension sets, Irrigation Syringes, Irrigation Sets, Umbilical Cord Clamps, Seldinger Needles, Brachytherapy Seeding Needles, Safe Syringes, Protective Cap, Infusion Connector, Stopcocks, Transfer Spikes, Oral Syringes, Injection Kits, Enteral Syringes, Syringes with Re-use Prevention Feature with Needle, Syringes with Re-use Prevention Feature without Needle, Syringes with Shielded-Needle, Drawing-up Filter Straw, Infusion Pump Administration Sets, Zero Residual Small Volume Syringe, Neuraxial Fit Tip Syringe, Zero Residual Small Volume Syringe without Needle, Irrigation Needles, Fistula Needles, Dental Operation Instruments (Odontotomaculum, Odontoscope), Infusion Bags' for Single Use, Syringes for Use with Power-driven Syringe Pumps, Sterile 'Medical Needles, Blood-collecting Needles, Dental Needles, Insulin Pen Needles, Blunt Filter Needle, Anaesthesia Needles, Heparin Caps, Huber Needles' for Single Use.

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Production of Sterile 'Seldinger Needles, Brachytherapy Seeding Needles, Injection Kits, Irrigation needles' for Single Use.

Shanghai Kindly Enterprise Development Group Co., Ltd.  
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Production of Sterile 'Syringes, Syringes for Insulin, Irrigation Sets, Umbilical Cord Clamps, Seldinger Needles, Brachytherapy Seeding Needles, Safe Syringes, Protective Cap, Infusion Connector, Stopcocks, Transfer Spikes, Oral Syringes, Injection Kits, Enteral Syringes, Syringes with Re-use Prevention Feature with Needle, Syringes with Re-use Prevention Feature without Needle, Syringes with Shielded-Needle, Zero Residual Small Volume Syringe, Neuraxial Fit Tip Syringe, Zero Residual Small Volume Syringe without Needle, Irrigation Needles' for Single Use, Syringes for Use with Power-driven Syringe Pumps.