



Certificate

No. Q5 077591 0019 Rev. 02

Holder of Certificate: **Hitec Medical Co., Ltd.**
No. 501, Building 2 Lane 1505, Lian Hang road
Minhang District
201112 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development,
Production and Distribution of
Medical Devices (For detail information see attachment)**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 077591 0019 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_077591_0019_Rev._02)

Report No.: SH2370901
Valid from: 2023-11-03
Valid until: 2026-11-02

Date, 2023-11-01

Christoph Dicks
Head of Certification/Notified Body

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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): **Hitec Medical Co., Ltd.**
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See Scope of Certificate

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Design, Development, Production and Distribution of

Sterile Urethral Catheters, Sterile Tracheostomy Tube, Sterile Silicone Foley Catheter, Sterile Foley Catheter with Temperature Sensor

Production and Distribution of

Sterile Tracheal Tube, Oxygen Mask, Sterile Connecting Tube with Yankauer Handle, Sterile Laryngeal Mask Device, Sterile Intubating Stylet, Non-rebreath Mask, Tracheostomy Mask, Aerosol Mask, Multi-vent mask, Sterile Stomach Tube, Sterile Silicone Stomach Tube, Sterile Suction Catheter, Sterile Feeding Tube, Sterile Nelaton Catheter, Sterile Tracheobronchial Tube, Sterile Reinforced Endotracheal Tube, Sterile Endotracheal Tube Introducer, Nasal Oxygen Cannula, Nebulizer, Disposable Air Cushion Face Mask, Sterile Endotracheal Tube Kit, Disposable Sterile Breathing Circuits, Sterile Heat and Moisture Exchange Filter, Manual Resuscitator, Sterile Silicone Tube, Sterile Endobronchial Blocker Tube, Sterile Ureteral Stent Set, Sterile Drainage System, Sterile Silicone Drainage System, Sterile Endotracheal Tube with Evacuation Lumen, Sterile Oropharyngeal Airway, Disposable Sterile Rectal Tube, Sterile Nasopharyngeal Airway, Sterile Urine Bag, Sterile Spigot, Sterile Safety Self-destructive Syringe(with Needle), Disposable Sterile Insulin Syringes for Single Use, Disposable Sterile Transfusion Set(with Needle), Disposable Sterile Hypodermic Syringes for Single Use (with Needle), Disposable Sterile Hypodermic Needles, Disposable Sterile Infusion Sets for Single Use(with Needle), Disposable Sterile Scalp Vein Sets, Disposable Sterile Hemodialysis Blood Circuits for Single Use, Sterile Closed Suction System