



Product Service

CERTIFICATE

No. Q5 17 08 77591 015

Holder of Certificate: **Hitec Medical Co., Ltd.**
 No. 703, Hengnan RD 1328
 Minhang District
 201114 Shanghai
 PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Hitec Medical Co., Ltd.
 No. 703, Hengnan RD 1328, Minhang District,
 201114 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)

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

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). See also notes overleaf.

Report No.: SH1770907

Valid from: 2017-11-03

Valid until: 2020-11-02



Stefan Preiß

Date, 2017-10-23

Page 1 of 2



Attachment for Certificate No Q5 17 08 77591 015

Supplement 001 dated 2017-10-23



Product Service

For the product(s)/product category (ies):

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

Munich, 2017-10-23

Stefan Preiß

Certification Medical Technology

Page 2 of 2