



Product Service

Certificate

No. Q5 077591 0019 Rev. 00

Holder of Certificate: **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)

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. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5_077591_0019_Rev.00)

Report No.: SH2070901
Valid from: 2020-11-03
Valid until: 2023-11-02

Date, 2020-11-03

Christoph Dicks
 Head of Certification/Notified Body





Product Service

Certificate

No. Q5 077591 0019 Rev. 00

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





Product Service

Certificate

No. Q5 077591 0019 Rev. 00

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





Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 17 08 77591 016

Facility(ies):

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

Attachment for Certificate No G2 17 08 77591 016

Supplement 001 dated 2017-10-23



Product Service

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

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,
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

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Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 17 08 77591 018

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



EC-Representative: **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies): **Urethral Catheters, Tracheostomy Tube, Silicone Foley Catheter, Foley Catheter with Temperature Sensor**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH1770907

Valid from: 2017-10-23

Valid until: 2021-11-02



Date, 2017-10-23

S. Preiß

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

EC Certificate**Full Quality Assurance System**

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 17 08 77591 018**Facility(ies):**

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