



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

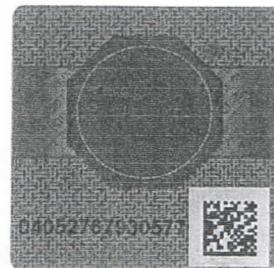


The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** SH1770907

**Valid from:** 2017-11-03

**Valid until:** 2020-11-02



*S. Preiß*

**Date,** 2017-10-23

Stefan Preiß

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DAKkS  
Deutsche  
Akreditierungsstelle  
D-ZM-11321-01-00

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

*S. Preiß*

Stefan Preiß

Certification Medical Technology



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**DAKKS**  
 Deutsche  
 Akkreditierungsstelle  
 D-ZM-11321-01-00





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 16 09 77591 012

**Manufacturer:****Hitec Medical Co., Ltd.**

No. 1328, Hengnan RD, 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.:**

SH16709EXT01

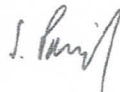
**Valid from:**

2016-11-03

**Valid until:**

2021-11-02

**Date,** 2016-10-10

  
Stefan Preis



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 16 09 77591 012**

**Facility(ies):**

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





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 16 09 77591 013

**Manufacturer:** **Hitec Medical Co., Ltd.**  
No. 1328, Hengnan RD, 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):** **For detailed information please see attachment**

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

**Report No.:** SH16709EXT01

**Valid from:** 2016-11-03  
**Valid until:** 2021-11-02



**Date,** 2016-10-11

*Stefan Preis*  
Stefan Preisß

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Attachment for Certificate No G2 16 09 77591 013

Supplement 001 dated 2016-10-11



Product Service

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

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, 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

Munich, 2016-10-11

Stefan Preiß

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Product Service

# EC Certificate

## Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 16 09 77591 014

**Manufacturer:** **Hitec Medical Co., Ltd.**  
 No. 1328, Hengnan RD, Minhang District  
 201414 Shanghai  
 PEOPLE'S REPUBLIC OF CHINA



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

**Product Category(ies):** **Oropharyngeal Airway,  
 Disposable Rectal Tube,  
 Nasopharyngeal Airway,  
 Urine Bag, Spigot**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

**Report No.:** SH16709EXT01

**Valid from:** 2016-11-03  
**Valid until:** 2021-11-02



**Date,** 2016-10-10

Stefan Preiß

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

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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

**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):** **Tracheal Tube, Oxygen Mask, Connecting Tube (Yankauer Handle)**  
(more details see attachment)

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

**Report No.:** SH1770907

**Valid from:** 2017-10-23  
**Valid until:** 2021-11-02



**Date,** 2017-10-23

*J. Preiß*  
Stefan Preiß

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

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Product Service

Attachment for Certificate No G2 17 08 77591 016

Supplement 001 dated 2017-10-23

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

*S. Preis*

Stefan Preis  
 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



*S. Preiß*

**Date,** 2017-10-23  
Stefan Preiß

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

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