ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
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:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

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

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

Date, 2020-11-03

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Iarovoi Petru
Date: 2021.01.08 14:55:01 EET
Reason: MoldSign Signature
Location: Moldova

FIRMA DE PRODUCERE SI COMERT "SOGNO" S.R.L. SINAU
Sogno

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany
TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Stefan Preiß

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

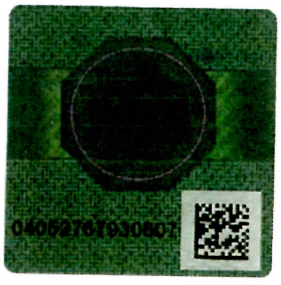
Product Category(ies):

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

Stefan Preiß

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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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