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®

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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

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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

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HITECARE Hitec Solutions

Hitec Medical Co., Ltd

Address: No. 703, Hengnan road 1328 Minhang District 201114 Shanghai P.R.C
Tel: 00 86 21 6429 6678 Fax: 00 86 21 6429 6676
www.hitecmed.com

Declaration of Conformity

Manufacturer: Hitec Medical Co., Ltd
No. 703, Hengnan road 1328 Minhang District 201114 Shanghai P.R.C

We declare under our sole responsibility that"

The medical devices: Endotracheal tube, Reinforced Endotracheal Tube ,Tracheostomy tube,PVC laryngeal mask,Silicone laryngeal mask,Latex foley catheter,Silicone foley catheter,Suction connecting tube with Yancauer handle,Catheter Mount,,Epidural Kit,Spinal Needle,Nazal oxygen cannula,Oxygen mask,Manual Resuscitator.

Models:

HTC0120U,HTC0125U,HTC0130U,HTC0135U,HTC0140U,HTC0145U,HTC0150U,HTC0155U,HTC0160U,HTC0165U,HTC0170U,HTC0175U,HTC0180U,HTC0185U,HTC0190U,HTC0195U,HTC0100U,HTC0125C,H0130C,HTC0135C,HTC0140C,HTC0145C,HTC0150C,HTC055C,HTC0160C,HTC0165C,HTC0170C,HTC0175C,HTC0180C,HTC0185C,HTC0190C,HTC0195C,HTC0110C,HTC0330C,HTC0335C,HTC0340C,HTC0345C,HTC0350C,HTC0355C,HTC0360C,HTC0365C,HTC0370C,HTC0375C,HTC0380C,HTC0385C,HTC0390C,HTC0395C,HTC0300C,HTC0530C,HTC0535C,HTC0540C,HTC0545C,HTC0550C,HTC0555C,HTC0560C,HTC0570C,HTC0575C,HTC0580C,HTC0585C,HTC0590C,HTC0810,HTC0820,HTC0825,HTC0830,HTC0840,HTC0850,HTC0910,HTC0915,HTC0920,HTC0925,HTC0930,HTC0940,HTB0406R,HTB0408R,HTB0410R,HTB0512R,HTB0514R,HTB0516R,HTB0518R,HTB0520R,HTB0522R,HTB0524R,HTB0526R,HTB0316,HTB0318,HTB0320,HTB0322,HTB0324,HTB0326,HTB0106,HTB0108,HTB0110,HTB0212,HTB0214,HTB0216,HTB0218,HTB0220,HTB0222,HTB0224,HTB0226,HTB0316,HTB0318,HTB0320,HTB0322,HTB0324,HTB0326,HTD201,HTD202,HTD203,HTD204,HTA1006,HTA1016,HTA1026,HTI0316,HTI0318,HTI0118QI,HTI0119QI,HTI0120QI,HTI0121QI,HTI0122QI,HTI0123QI,HTI0124QI,HTI0125QI,HTI0126QI,HTI0127QI,HTA0701,HTA0702,HTA0703,HTA0704,HTA0101,HTA0102,HTA0103,HTA0104,HTA1401,HTA1402,HTA1403,HTA1404,HTA1405,HTA1406

Of class IIa, rule 5 according to Annex IX of 93/42/EEC Directive.

HITECARE Hitec Solutions

Hitec Medical Co., Ltd

Address: No. 703, Hengnan road 1328 Minhang District 201114 Shanghai P.R.C
Tel: 00 86 21 6429 6678 Fax: 00 86 21 6429 6676
www.hitecmed.com

Covered by the technical files rev.01. dated 2013 product releasing documentation: departmental Norm No. 01/2001, ver. 05, technological instruction No. And lot report No. BA 331 which is consiered as a part of this declaration.

Meets the provisions of the directive 93/42/EEC which apply to them.

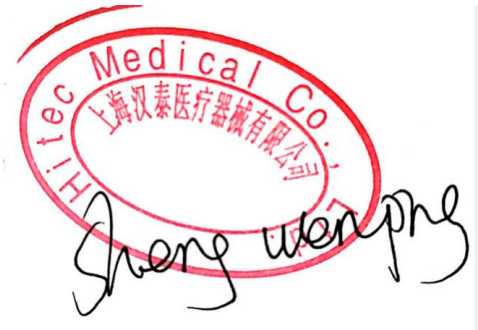
UMDNS CODE: 10-767

APPLIED HARMONIZED STANDARDS:

All applicable harmonized Standard (published in the Official Journal of the European Communities) ENISO13485： 2003/AC： 2009, ENISO14971:2009, ENISO10993-1:2009, ENISO10993-5:2009, ISO 10993-7:2008, ENISO10993-10:2010, ENISO10993-11:2009, ENISO10993-12:2007, EN980:2008, EN1041:2008, EN556:2001, ENISO14155-1:2003, ENISO14155-2:2003, ISO14644-1:1999, ENISO11607-1:2009, ENISO11607-2:2009, ENISO11737-1:2006, ENISO11737-2:2006, ENISO11135-1:2007, ISO11138-1:2006, ISO11138-2:2006, EN 62366:2008, EN1616:1997, MEDDEV. 2.7.1 Rev.3

Conformity assessment procedure: Ⅱb MDD Annex IX, rule 5

NOTIFIED BODY:ÜV SÜD Product Service GmbH, Ridlestrasse. 65,80339 München, Germany
Identification Number: 0123
Signature of issue person:
Position: General Manager
Name: Mr. Sheng, Wenping
Date: 2021-12-20
Place: Shanghai



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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 077591 0020 Rev. 00

Manufacturer

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

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. 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:G2S 077591 0020 Rev. 00

Report No.: SH21709EXT01

Valid from: 2021-05-12
Valid until: 2024-05-26
Date, 2021-05-12

Christoph Dicks
Head of Certification/Notified Body

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

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