



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

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

Christoph Dicks
 Head of Certification/Notified Body

Date, 2020-11-03





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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**



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.

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 considered 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: II b 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

