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

Product Se

CERTIFICATE

No. Q5 17 08 77591 015

Digitally signed by Iarovoi Petru
Date: 2019.02.01 16:57:18 EET
Reason: MoldSign Signature
Location: Moldova

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:

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)**

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

FIRMA DE PRODUCERE ȘI COMERȚ "SOGNO S.R.L." IDNO 1004600013854 REPUBLICA MOLDOVA, mun. CHIȘINĂU

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

Date, 2017-10-23

Stefan Preiß

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

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

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

(6)

Munich, 2017-10-23

I. Preiß

Stefan Preiß

Certification Medical Technology

FIRMA DE PRODUCERE ȘI COMERȚ SOGNO S.R.L. Sogno S.R.L. IDNO 1004600013854 REPUBLICA MOLDOVA, mun CHIȘINĂU

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

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ 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 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 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 16 09 77591 012

Facility(ies):

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

FIRMA DE PRODUCERE ŞI COMERŢ "SOGNO" S.R.L. REPUBLICA MOLDOVA, mun. CHIŞINĂU IDNO 1004600013854 Sogno® S.R.L.

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

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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 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 Preiß

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

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

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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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 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
201114 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

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

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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

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FIRMA DE PRODUCERE SI COMERT "SOGNO" S.R.L. REPUBLICA MOLDOVA

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

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 17 08 77591 017

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):

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.: 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 ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD
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

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