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 15 04 73403 017

Manufacturer:

Henan Tuoren Medical Device Co., Ltd.
Weiyuan Industrial Zone
Menggang, Changyuan County
453400 Henan
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Well Kang Limited
The Black Church, St. Mary's Place
Dublin 7
IRELAND

Product Category(ies):

Endotracheal Tube, Tracheotomy Tube, Endobronchial Tube, Infusion Pump, I.V,Cannula, Reinforced Endotracheal Tube, Laryngeal Mask Airway, Foley Catheter Kit, Suction Catheter, Breathing Circuit, Oxygen Mask, Anesthesia Mask, Guedel Airway and Endotracheal Intubation kit, Disposable central venous catheter kit, Anaesthesia Kit and Anaesthesia Needle, Nasal Oxygen Tube, Heat and moisture exchanger, Suction Handle,Manual resuscitator.

Digitally signed by Iarovoi Petru
Date: 2019.02.01 17:13:19 EET
Reason: MoldSign Signature
Location: Moldova

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.: BJ1573707

Valid from: 2015-11-29
Valid until: 2020-11-28

Date, 2015-09-07

Hans-Heiner Junker

04052768710048

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ 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 15 04 73403 017

Facility(ies):

Henan Tuoren Medical Device Co., Ltd.
Weiyuan Industrial Zone, Menggang, Changyuan County, 453400
Henan, PEOPLE'S REPUBLIC OF CHINA

Henan Tuoren Medical Device Co., Ltd.
Mancun Industrial Zone, Changyuan County, 453400 Henan,
PEOPLE'S REPUBLIC OF CHINA

Henan Tuoren Medical Device Co., Ltd.
Middle of Weft 7 Road, Nampu District, Changyuan County,
453400 Henan, PEOPLE'S REPUBLIC OF CHINA

FIRMA DE PRODUCERE ȘI COMERȚ "SOGNO" S.R.L.
Sogno S.R.L.
IDNO 1004800013854
REPUBLICA MOLDOVA, mun. CHIȘINĂU

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TÜV SÜD 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 15 04 73403 018

Manufacturer: **Henan Tuoren Medical Device Co., Ltd.**
Weiyuan Industrial Zone
Menggang, Changyuan County
453400 Henan
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **Well Kang Limited**
The Black Church, St. Mary's Place
Dublin 7
IRELAND

Product Category(ies):
Connecting Tube,
Disposable infusion connection tube,
Disposable Suction Drainage Bag.

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.: BJ1573707

Valid from: 2015-11-29
Valid until: 2020-11-28

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Date, 2015-09-07

Hans-Heiner Junker

04052768710062

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 I in sterile conditions, sterilised systems or procedure packs)

No. G2S 15 04 73403 018

Facility(ies):

Henan Tuoren Medical Device Co., Ltd.
Weiyuan Industrial Zone, Menggang, Changyuan County, 453400
Henan, PEOPLE'S REPUBLIC OF CHINA

Henan Tuoren Medical Device Co., Ltd.
Mancun Industrial Zone, Changyuan County, 453400 Henan,
PEOPLE'S REPUBLIC OF CHINA

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TÜV SÜD Product Service

CERTIFICATE

No. Q1N 17 01 73403 024

Holder of Certificate: **Henan Tuoren Medical Device Co., Ltd.**
Weiyuan Industrial Zone
Menggang, Changyuan County
453400 Henan
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

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

Scope of Certificate:

Design, Development, Production and Distribution of Infusion Pump, I.V. Cannula, Endotracheal Tube, Reinforced Endotracheal Tube, Tracheotomy Tube, Endobronchial Tube, Laryngeal Mask Airway, Connecting Tube, Foley Catheter Kit, Suction Catheter, Breathing Circuit, Oxygen Mask, Anesthesia Mask, Guedel Airway, Endotracheal Intubation Kit,Disposable central venous catheter kit, Anaesthesia Kit and Anaesthesia Needle, Manual resuscitator, Disposable Infusion Connection Tube, Suction Drainage Bag, Disposable Suction Drainage Bag, Nasal Oxygen Tube, Suction Handle, Heat and moisture exchanger, Disposable pressure transducer, Electronic infusion pump, LOR Indicator Syringe.

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.: BJ16737041

Valid from: 2017-07-25
Valid until: 2019-11-28

Date, 2017-07-25

Stefan Preiß

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

Product Service

CERTIFICATE
No. Q1N 17 01 73403 024

Applied Standard(s):

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

Facility(ies):

Henan Tuoren Medical Device Co., Ltd.
Weiyuan Industrial Zone, Menggang, Changyuan County, 453400 Henan, PEOPLE'S REPUBLIC OF CHINA

Henan Tuoren Medical Device Co., Ltd.
Mancun Industrial Zone, Changyuan County, 453400 Henan, PEOPLE'S REPUBLIC OF CHINA

Henan Tuoren Medical Device Co., Ltd.
Middle of Weft 7 Road, Nampu District, Changyuan County, 453400 Henan, PEOPLE'S REPUBLIC OF CHINA

FIRMA DE PRODUCERE ȘI COMERȚ SOGNO S.R.L. REPUBLICA MOLDOVA, mun. CHIȘINĂU IDNO 1004600013954

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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 01 73403 025

Manufacturer:

Henan Tuoren Medical Device Co., Ltd.
Weiyuan Industrial Zone
Menggang, Changyuan County
453400 Henan
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Well Kang Limited
The Black Church, St. Mary's Place
Dublin 7
IRELAND

Product Category(ies):

Endotracheal Tube, Tracheotomy Tube,
Endobronchial Tube, Infusion Pump,
I.V,
Cannula, Reinforced Endotracheal Tube,
Laryngeal Mask Airway, Foley Catheter Kit,
Suction Catheter, Breathing Circuit, Oxygen Mask,
Anesthesia Mask,
Guedel Airway and Endotracheal Intubation Kit,
Disposable central venous catheter kit,
Anaesthesia Kit and Anaesthesia Needle,
Nasal Oxygen Tube, Heat and moisture exchanger,
Suction Handle,
Manual resuscitator,
LOR Indicator Syringe.

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.: BJ16737041

Valid from: 2017-07-25
Valid until: 2020-11-28

Date, 2017-07-25

Stefan Preiß

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

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(Devices in Class IIa, IIb or III)

No. G1 17 01 73403 025

Facility(ies):

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