



ET Tube Introducers ① (Bougies)

- Solid type
- for difficult intubation and tube exchange
- Ultra smooth surface for low friction
- Atraumatic tip to minimize risk of patient trauma
- Scale mark indicates distance to the tip
- With or without angled tip

ET Tube Introducers ② (Bougies)

- Hollow type
- Allow delivery of oxygen in emergency
- O2 Connector available upon request

Premium ET Tube Introducers ③ (Bougies)

- Solid type
- Premium bougie range with high gloss, low friction outer surface to improve tube glide over bougie
- Robust outer tube prevents damage in transit and storage
- Highly visible colour for improved positioning in poor light
- Scale mark indicates distance to the tip
- With or without angled tip

Premium ET Tube Introducers ④ (Bougies)

- Hollow type
- Allow delivery of oxygen in emergency
- O2 Connector available upon request

O2 connector

Cat.no.
99370000

ET Tube Introducers (Bougies, solid type)

Cat.no.	Size (Fr/Ch)
26210600	6FR
26211000	10FR
26211500	15FR

ET Tube Introducers (Bougies, hollow type)

Cat.no.	Size (Fr/Ch)
26221000	10FR
26221500	15FR

Premium ET Tube Introducers (Bougies, solid type)

Cat.no.	Size (Fr/Ch)
26250500	5FR
26251000	10FR
26251500	15FR

Premium ET Tube Introducers (Bougies, hollow type)

Cat.no.	Size (Fr/Ch)
26261000	10FR
26261400	14FR



Certificat CE

Nr. Q1N 16 05 38814 061

Titularul Certificatului:

Well Lead Medical Co., Ltd.

C-4 Jinhu Industrial Estate, Hualong

511434 Panyu, Guangzhou

REPUBLICA POPULARA CHINEZA

Facilitati de productie:

Well Lead Medical Co., Ltd.

C-4 Jinhu Industrial Estate, Hualong, 511434 Panyu, Guangzhou,

REPUBLICA POPULARA CHINEZA

Well Lead Medical Co., Ltd.

No 47 Guomao Avenue South, 511434 Panyu, Guangzhou,

REPUBLICA POPULARA CHINEZA



Marcaj de certificare: Product Service

Obiectul certificatului: Proiectarea si dezvoltarea, productia si distributia dispozitivelor medicale (pentru informatii detaliate, consultati anexa).

Standarde aplicabile:

EN ISO 13485:2012 + AC:2012

Dispozitive medicale – sisteme de management al calitatii – cerinte in scopul regloementarii (ISO 13485:2003 + Cor. 1:2009), DIN EN ISO 13485:2012

Organul de certificare TUV SUD Product Service GmbH declara ca sus-mentionatul producator a stabilit si mentine un sistem de management al calitatii care respecta cerintele standardelor mentionate. Consultati si notele de pe verso.

Raport nr. SH1608018

Valabil de la: 2016-09-06

Valabil pana la: 2019-08-19

TUV SUD Product Service GmbH este un organ de certificare cu nr. de identificare 0123.

Pagina 1 din 2 (Semnatura indescifrabila) Stefan Preiss

TUV SUD Product Service GmbH * Organ de certificare * Ridlerstrasse 65 *
80339 Muenchen * Germania



Anexa la Certificatul nr. Q1N 16 05 38814 061
Anexa 001 din data de 2016-09-05

Pentru produsele / categoriile de produse:

Proiectarea si dezvoltarea, productia si distributia de:

Catetere uretrale si tuburi traheale, tuburi de traheostomie, tuburi de aer orofaringeale, catetere de suctiune, specule nazale, tuburi conectoare cu maner Yankauer, urometre, tuburi stomacale, stilete de intubare, tuburi de suctiune pentru ingrijire orala, catetere Foley fabricate integral din silicon, canule nazale pentru oxigen, sisteme de gestionare a fecalelor, masti laringeale, tuburi traheobronhiale, masti respiratorii antiretur, masti de traheostomie, masti de oxigen, catetere Nelaton, tuburi endotraheale ranforsate, de tuburi endotraheale, tuburi rectale de unica folosinta, catetere Foley cu senzor de temperatura, atomizoare, tuburi nasofaringiale, stilete, seturi de catetere Foley, masti faciale de unica folosinta pentru aer, seturi de tuburi endotraheale, catetere pentru oxigen, HMEF (filtre schimbatoare de caldura si umiditate), tuburi din silicon, aparate manuale de resuscitare, sisteme de drenare, tuburi de alimentare, lame laringoscopice, de extractie (de uz chirurgical), clipuri (implant de lentile), spigoturi, seturi stent uretral, autocatetere hidrofile, tuburi endotraheale cu lumen de evacuare, sisteme de drenare din silicon, masti pentru aerosoli, pungi pentru urina, tuburi T pentru bila, tuburi de traheostomie cu canula interna, masti de multiventilatie, seringi umplute cu gel lubrifiant, sisteme de auto-cateterizare de unica folosinta, seringi umplute cu apa purificata sau 10% glicerina, masti de prelevare de CO2 pentru capnografie, canule de prelevare O2+CO2, masti de ventilatie noninvaziva cu presiune pozitiva, suporturi pentru catetere, pungi pentru respiratie, seturi de tuburi pentru traheostomie, tuburi pentru gastrostomie, tuburi pentru acces uretral, catetere uretrale cu balon dilatator, aparat circulator pentru purificarea extracorporala a sangelui, catetere externe, circuite respiratorii pentru anestezie, seturi de dilatare, tuburi de acces pentru suctiune-evacuare, punctie fistula vezicala, fir de ghidaj, tub de injectie nazala, catetere uretrale fara balon, cosuri de retinere a calculilor, catetere uretrale.

Munich, MHS-CRT, 2016-09-05
(Semnatura indescifrabila)
Stefan Preiss

Pagina 2 din 2

TUV SUD Product Service GmbH * Organ de certificare * Ridlerstrasse 65 *
80339 Muenchen * Germania





Certificat CE

Sistem de asigurare a calitatii in productie

Directiva 93/42/CEE privind dispozitivele medicale

Anexa V (Dispozitive din Clasa IIa, IIb sau III)

Nr. G2 16 05 38814 062

Producator:

Well Lead Medical Co., Ltd.

C-4 Jinhu Industrial Estate, Hualong

511434 Panyu, Guangzhou

REPUBLICA POPULARA CHINEZA

Reprezentant in CE:

Shanghai International Holding Corp. GmbH (Europa)

Eiffestrasse 80

20537 Hamburg

GERMANIA

Categorii de produse: Pentru informatii detaliate, consultati anexa.

Organul de certificare TUV SUD Product Service GmbH declara ca sus-mentionatul producator a implementat un sistem de asigurare a calitatii pentru fabricarea si inspectia finala a respectivelor dispozitive / categorii de dispozitive, conform DDM, Anexa V. Acest sistem de asigurare a calitatii respecta cerintele Directivei si constituie obiectul supravegherii continue. Un certificat suplimentar, conform Anexei III, este obligatoriu pentru comercializarea dispozitivelor din clasele IIb si III. Consultati si notele de pe verso.

Raport nr. SH1608018

Valabil de la: 2016-09-06

Valabil pana la: 2020-08-23

TUV SUD Product Service GmbH este un organ de certificare cu nr. de identificare 0123.

Pagina 1 din 3

TUV SUD Product Service GmbH * Organ de certificare * Ridlerstrasse 65 *
80339 Muenchen * Germania





Product Service

Certificat CE

Sistem de asigurare a calitatii in productie

Directiva 93/42/CEE privind dispozitivele medicale

Anexa V (Dispozitive din Clasa IIa, IIb sau III)

Nr. G2 16 05 38814 062

Facilitati de productie:

Well Lead Medical Co., Ltd.

C-4 Jinhua Industrial Estate, Hualong, 511434 Panyu, Guangzhou,
REPUBLICA POPULARA CHINEZA

Well Lead Medical Co., Ltd.

No 47 Guomao Avenue South, 511434 Panyu, Guangzhou,
REPUBLICA POPULARA CHINEZA



Anexa la Certificatul nr. G2 16 05 38814 062
Anexa 001 din data de 2016-09-05

Pentru produsele / categoriile de produse:

Catetere uretrale si tuburi traheale, catetere Nelaton, tuburi conectoare cu maner Yankauer, stilele de intubare, masti laringeale, tuburi traheobronhiale, tuburi endotraheale ranforsate, atomizoare, masti de oxigen, masti respiratorii antiretur, masti de traheostomie, masti pentru aerosoli, masti de multiventilatie, introductoare de tuburi endotraheale, canule nazale pentru oxigen, stilete, masti faciale de unica folosinta pentru aer, seturi de tuburi endotraheale, HMEF (filtre schimbatoare de caldura si umiditate), aparate manuale de resuscitare, sisteme de drenare, catetere pentru oxigen, tuburi de silicon, tuburi de blocare endobronhiala, pungi de extractie (de uz chirurgical), seturi stent uretral, sisteme de drenare din silicon, tuburi endotraheale cu lumen de evacuare, catetere de suptiune, tuburi de alimentare, tuburi stomacale, tuburi stomacale din silicon, sisteme de auto-cateterizare de unica folosinta, masti de prelevare de CO2 pentru capnografie, canule de prelevare O2+CO2, masti de ventilatie noninvaziva cu presiune pozitiva, tuburi de suptiune pentru ingrijire orala, tuburi T pentru bila, sisteme de gestionare a fecalelor, autocatetere hidrofile, tuburi de acces uretral, catetere uretrale cu balon dilatator, circuite respiratorii pentru anestezie, seturi de dilatatie, tuburi de acces pentru suptiune-evacuare, punctie fistula vezicala, fir de ghidaj, tub de injectie nazala, catetere uretrale fara balon, cosuri de retinere a calculilor, catetere uretrale.

Munich, MHS-CRT, 2-016-09-05
Semnatura indescifrabila)
Stefan Preiss

Pagina 3 din 3

TUV SUD Product Service GmbH * Organ de certificare * Ridlerstrasse 65 *
80339 Muenchen * Germania





Product Service

CERTIFICATE

No. Q1N 16 05 38814 061

Holder of Certificate: Well Lead Medical Co., Ltd.

C-4 Jinhu Industrial Estate, Hualong
511434 Panyu, Guangzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Well Lead Medical Co., Ltd.
C-4 Jinhu Industrial Estate, Hualong, 511434
Panyu, Guangzhou, PEOPLE'S REPUBLIC OF
CHINA

Well Lead Medical Co., Ltd.
No 47 Guomao Avenue South, 511434 Panyu,
Guangzhou, PEOPLE'S REPUBLIC OF CHINA


Certification Mark:


Scope of Certificate: Design and Development,
Production and Distribution
of Medical Devices
(For detailed information see attachment)

**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

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.: SH1608018

Valid from: 2016-09-06
Valid until: 2019-08-19

Date, 2016-09-05

S. Preiß
Stefan Preiß

Page 1 of 2



Attachment for Certificate No Q1N 16 05 38814 061

Supplement 001 dated 2016-09-05



Product Service

For the product(s)/product category (ies):

Design and Development, Production and Distribution of
 Urethral Catheters and Tracheal Tubes, Tracheostomy Tubes, Oropharyngeal
 Airways, Suction Catheters, Nasal Speculas, Connecting Tubes with Yankauer
 Handle, Urine Meters, Stomach Tubes, Intubating Stylets, Suction Tubes of Oral
 Care, All Silicone Foley Catheters, All Silicone Stomach Tubes, Nasal Oxygen
 Cannulas, Fecal Management Systems, Laryngeal Mask Devices,
 Tracheobronchial Tubes, Non-Rebreath Masks, Tracheostomy Masks,
 Oxygen Masks, Nelaton Catheters, Reinforced Endotracheal Tubes,
 Endotracheal Tube Introducers, Disposable Rectal Tubes, Foley Catheters
 with Temperature Sensor, Nebulizers, Nasopharyngeal Airways, Stylets, Foley
 Catheter Kits, Disposable Air Cushion Face Masks, Endotracheal Tube Kits,
 Oxygen Catheters, HMEF (Heat and Moisture Exchanger Filters), Silicone Tubes,
 Manual Resuscitators, Drainage Systems, Feeding Tubes, Endobronchial Blocker
 Tubes, Laryngoscope Blades, Extraction Bags (Operation Uses), Clip-Its (Lens
 Implantation), Spigots, Ureteral Stent Sets, Self Hydrophilic Catheters, Silicone
 Drainage Systems, Aerosol Masks, Urine Bags, Endotracheal Tubes with
 Evacuation Lumen, Bile T-Tubes, Tracheostomy Tubes with Inner Cannula, Multi-
 vent Masks, Prefilled Syringes with Lubricating Jelly, Disposable Self-
 Catheterization Systems, Prefilled Syringes with Purified Water or 10% Glycerin
 Solution Capnography CO2 Sampling Masks, O2+CO2 Sampling Cannulas,
 Non-invasive Positive Pressure Ventilation Masks, Catheter Holders, Breathing
 Bags, Tracheostomy Tube Kits, Gastrostomy Tubes, Ureteral Access Sheaths,
 Ureteral Dilation Balloon Catheters, Extracorporeal Circulation Conduct of Blood
 Purification Apparatus, Urodynamic Catheters, Rectal Pressure Catheters,
 Anesthetic Breathing Circuits, Male External Catheters, Dilation Sets, Suction-
 Evacuation Access Sheaths, Bladder Puncture Fistula, Guide Wire, Nasal Jet
 Tubes, Urethral Catheters without Balloon, Stone Retrieval Baskets, Urethral
 Catheters

Munich, MHS-CRT, 2016-09-05

Stefan Preiß

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