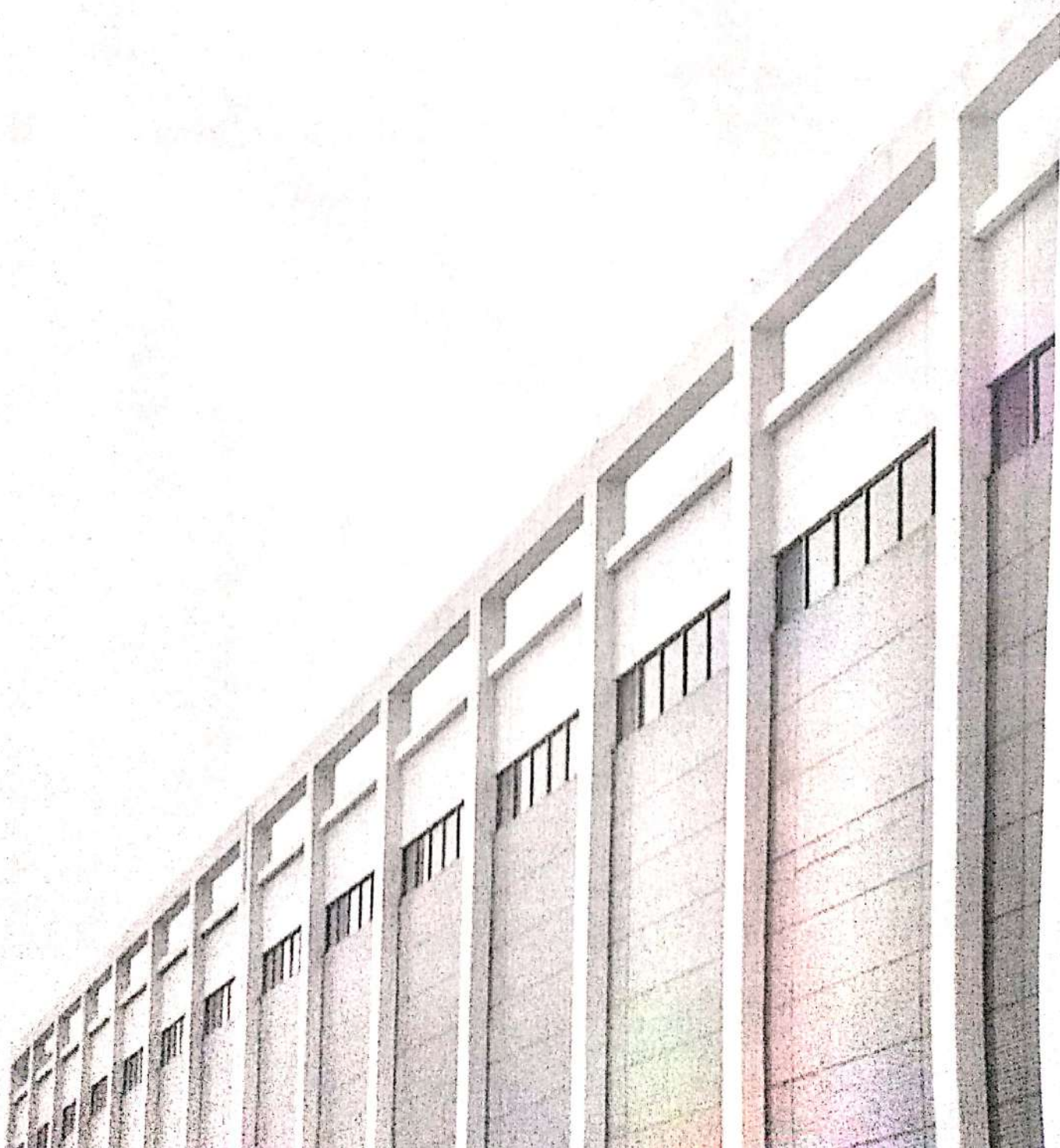


Founded in 1998, Well Lead Medical Group is one of the leading companies in China which specialize in the development, manufacturing and distribution of disposable medical products. The head office, located in Guangzhou, is the production and R&D base of the group. It covers an area of 60,000 m², with an 18,000 m² class 100,000 cleanroom and a R&D center equipped with 4 laboratories for technology, physics, chemistry and microorganism study. The product lines cover the area of Anesthesia, Respiratory, Urology and Hemodialysis. As an ISO 13485 certified CO, Well Lead Medical strictly abides by ISO standard and international practice. All products have obtained CE certificates and some of them are FDA registered. In Well Lead, all staff holds the same belief—We care for patients with quality products. We believe these core values have made Well Lead the company that it is today.

wellead

<http://www.wellead.com.cn>



◆ Endotracheal Tube Introducer (Bougie)



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 (Bougies) 3

- 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 (Bougies) 4

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

O2 connector

Catno.
99370000

Premium ET Tube Introducers (Bougies, hollow type)

Catno.	Size (Fr)
26261000	10FR
26261400	14FR

Premium ET Tube Introducers (Bougies, solid type)

Catno.	Size (Fr)
26250500	5FR
26251000	10FR
26251500	15FR

ET Tube Introducers (Bougies, hollow type)

Catno.	Size (Fr)
26221000	10FR
26221500	15FR

ET Tube Introducers (Bougies, solid type)

Catno.	Size (Fr)
26210600	6FR
26211000	10FR
26211500	15FR



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 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



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

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80339 Muenchen * Germania

