

Declaration of Conformity

Manufacturer: **Well Lead Medical Co., Ltd.**
C-4 Jinhu Industrial Estate, Hualong 511434 Panyu, Guangzhou,
People Republic of China

European Representative: **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestrasse 80, 20537 Hamburg, GERMANY

Product Name:

Size: Endotracheal Tube Kit
I.D.3.0/ I.D.3.5 / I.D.4.0/ I.D.4.5/ I.D.5.0/ I.D.5.5/ I.D.6.0/ I.D.6.5/ I.D.7.0/
I.D.7.5/ I.D.8.0/ I.D.8.5/ I.D.9.0/ I.D.9.0/ I.D.10.0

UMDNS Code: 14085

Classification (MDD, Annex IX): **Ila, Rule 5**

Conformity Assessment Route: **Annex II excluding (4)**

We herewith declare in our sole responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. The declaration of conformity is issued under our sole responsibility.

DIRECTIVES

General applicable directives: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning Medical devices, amended by Council Directive 2007/47/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany

Identification number: CE0123

(EC) Certificate(s): **G1 038814 0086 Rev.01**

Expire date of the Certificate: **2024-05-26**

Start of CE Marking: **2008**

Place, Date of Issue: **Guangzhou, 2021-02-20**

Signature: 

Name: Chen Yun Gui

Position: **Management Representative**



Annex

Article Number	Well Lead's Description
845050	Endotracheal Tube Cuffed, Murphy 5.0MM, With Stylet and Syringe
845055	Endotracheal Tube Cuffed, Murphy 5.5MM, With Stylet and Syringe
845060	Endotracheal Tube Cuffed, Murphy 6.0MM, With Stylet and Syringe
845065	Endotracheal Tube Cuffed, Murphy 6.5MM, With Stylet and Syringe
845070	Endotracheal Tube Cuffed, Murphy 7.0MM, With Stylet and Syringe
845075	Endotracheal Tube Cuffed, Murphy 7.5MM, With Stylet and Syringe
845080	Endotracheal Tube Cuffed, Murphy 8.0MM, With Stylet and Syringe
845085	Endotracheal Tube Cuffed, Murphy 8.5MM, With Stylet and Syringe
845090	Endotracheal Tube Cuffed, Murphy 9.0MM, With Stylet and Syringe
849035-M	Reinforced ET Tube, Cuffed, Murphy, Size 3.5MM, Curved, With Curved Stylet
849040-M	Reinforced ET Tube, Cuffed, Murphy, Size 4.0MM, Curved, With Curved Stylet
849045-M	Reinforced ET Tube, Cuffed, Murphy, Size 4.5MM, Curved, With Curved Stylet
849050-M	Reinforced ET Tube, Cuffed, Murphy, Size 5.0MM, Curved, With Curved Stylet
849055-M	Reinforced ET Tube, Cuffed, Murphy, Size 5.5MM, Curved, With Curved Stylet
849060-M	Reinforced ET Tube, Cuffed, Murphy, Size 6.0MM, Curved, With Curved Stylet
849065-M	Reinforced ET Tube, Cuffed, Murphy, Size 6.5MM, Curved, With Curved Stylet
849070-M	Reinforced ET Tube, Cuffed, Murphy, Size 7.0MM, Curved, With Curved Stylet
849075-M	Reinforced ET Tube, Cuffed, Murphy, Size 7.5MM, Curved, With Curved Stylet
849080-M	Reinforced ET Tube, Cuffed, Murphy, Size 8.0MM, Curved, With Curved Stylet
849085-M	Reinforced ET Tube, Cuffed, Murphy, Size 8.5MM, Curved, With Curved Stylet
849635-M	Reinforced ET Tube, Magill Without cuff, With Stylet, 3.5mm
849640-M	Reinforced ET Tube, Magill Without cuff, With Stylet, 4.0mm
849645-M	Reinforced ET Tube, Magill Without cuff, With Stylet, 4.5mm
849650-M	Reinforced ET Tube, Magill Without cuff, With Stylet, 5.0mm
849655-M	Reinforced ET Tube, Magill Without cuff, With Stylet, 5.5mm
849660-M	Reinforced ET Tube, Magill Without cuff, With Stylet, 6.0mm
849665-M	Reinforced ET Tube, Magill Without cuff, With Stylet, 6.0mm