

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)**
Product Name: Eiffestrasse 80, 20537 Hamburg, GERMANY
Size: Tracheal Tube
UMDNS Code: Refer to Annex
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: **2003**
Place, Date of Issue: **Guangzhou, 2021-02-20**

Signature: _____

Name: Chen Yun Gui

Position: **Management Representative**



Annex

Variants of Tracheal Tube

Model	Size, I.D(mm)			
	Type			
	HVLP* cuffed	LP* cuffed	PU cuffed	Uncuffed
Standard Tracheal Tube	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0, 10.5, 11.0	2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0,	2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0, 10.5, 11.0
Oral Tracheal Tube	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0
Nasal Tracheal Tube	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0
Oral North	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0	/	/	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0
Softline Nasal Pre-formed	5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0	/	/	2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0
Microlaryngeal ET Tube	4.0, 5.0, 6.0	/	/	/

Parker Series

Model	Size, I.D(mm)			
	Type			
	HVLP* cuffed	LP* cuffed	PU cuffed	Uncuffed
Standard Tracheal Tube	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0,	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0,	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0
Oral Tracheal Tube	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0
Nasal Tracheal Tube	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0
Microlaryngeal ET Tube	4.0, 5.0, 6.0			/

Annex

Article Number	Product Description
840030	Endotracheal Tube, Cuffed, Magil Type, Size 3.0MM
840035	Endotracheal Tube, Cuffed, Magil Type, Size 3.5MM
840040	Endotracheal Tube, Cuffed, Magil Type, Size 4.0MM
840045	Endotracheal Tube, Cuffed, Magil Type, Size 4.5MM
840050	Endotracheal Tube, Cuffed, Magil Type, Size 5.0MM
840055	Endotracheal Tube, Cuffed, Magil Type, Size 5.5MM
840060	Endotracheal Tube, Cuffed, Magil Type, Size 6.0MM
840065	Endotracheal Tube, Cuffed, Magil Type, Size 6.5MM
840070	Endotracheal Tube, Cuffed, Magil Type, Size 7.0MM
840075	Endotracheal Tube, Cuffed, Magil Type, Size 7.5MM
840080	Endotracheal Tube, Cuffed, Magil Type, Size 8.0MM
840085	Endotracheal Tube, Cuffed, Magil Type, Size 8.5MM
840090	Endotracheal Tube, Cuffed, Magil Type, Size 9.0MM
840095	Endotracheal Tube, Cuffed, Magil Type, Size 9.5MM
840100	Endotracheal Tube, Cuffed, Magil Type, Size 10.0MM
841030	Endotracheal Tube, Cuffed, Murphy Type, Size 3.0MM
841035	Endotracheal Tube, Cuffed, Murphy Type, Size 3.5MM
841040	Endotracheal Tube, Cuffed, Murphy Type, Size 4.0MM
841045	Endotracheal Tube, Cuffed, Murphy Type, Size 4.5MM
841050	Endotracheal Tube, Cuffed, Murphy Type, Size 5.0MM
841055	Endotracheal Tube, Cuffed, Murphy Type, Size 5.5MM
841060	Endotracheal Tube, Cuffed, Murphy Type, Size 6.0MM
841065	Endotracheal Tube, Cuffed, Murphy Type, Size 6.5MM
841070	Endotracheal Tube, Cuffed, Murphy Type, Size 7.0MM
841075	Endotracheal Tube, Cuffed, Murphy Type, Size 7.5MM
841080	Endotracheal Tube, Cuffed, Murphy Type, Size 8.0MM
841085	Endotracheal Tube, Cuffed, Murphy Type, Size 8.5MM
841090	Endotracheal Tube, Cuffed, Murphy Type, Size 9.0MM
841095	Endotracheal Tube, Cuffed, Murphy Type, Size 9.5MM
841100	Endotracheal Tube, Cuffed, Murphy Type, Size 10.0MM
842020	Endotracheal Tube, Uncuffed, Magil Type, Size 2.0MM
842025	Endotracheal Tube, Uncuffed, Magil Type, Size 2.5MM
842030	Endotracheal Tube, Uncuffed, Magil Type, Size 3.0MM
842035	Endotracheal Tube, Uncuffed, Magil Type, Size 3.5MM
842040	Endotracheal Tube, Uncuffed, Magil Type, Size 4.0MM
842045	Endotracheal Tube, Uncuffed, Magil Type, Size 4.5MM
842050	Endotracheal Tube, Uncuffed, Magil Type, Size 5.0MM
842055	Endotracheal Tube, Uncuffed, Magil Type, Size 5.5MM
842060	Endotracheal Tube, Uncuffed, Magil Type, Size 6.0MM
842065	Endotracheal Tube, Uncuffed, Magil Type, Size 6.5MM

842070	Endotracheal Tube, Uncuffed, Magil Type, Size 7.0MM
842075	Endotracheal Tube, Uncuffed, Magil Type, Size 7.5MM
842080	Endotracheal Tube, Uncuffed, Magil Type, Size 8.0MM
842085	Endotracheal Tube, Uncuffed, Magil Type, Size 8.5MM
842090	Endotracheal Tube, Uncuffed, Magil Type, Size 9.0MM
842095	Endotracheal Tube, Uncuffed, Magil Type, Size 9.5MM
842100	Endotracheal Tube, Uncuffed, Magil Type, Size 10.0MM
843020	Endotracheal Tube, Uncuffed, Murphy Type, Size 2.0MM
843025	Endotracheal Tube, Uncuffed, Murphy Type, Size 2.5MM
843030	Endotracheal Tube, Uncuffed, Murphy Type, Size 3.0MM
843035	Endotracheal Tube, Uncuffed, Murphy Type, Size 3.5MM
843040	Endotracheal Tube, Uncuffed, Murphy Type, Size 4.0MM
843045	Endotracheal Tube, Uncuffed, Murphy Type, Size 4.5MM
843050	Endotracheal Tube, Uncuffed, Murphy Type, Size 5.0MM
843055	Endotracheal Tube, Uncuffed, Murphy Type, Size 5.5MM
843060	Endotracheal Tube, Uncuffed, Murphy Type, Size 6.0MM
843065	Endotracheal Tube, Uncuffed, Murphy Type, Size 6.5MM
843070	Endotracheal Tube, Uncuffed, Murphy Type, Size 7.0MM
843075	Endotracheal Tube, Uncuffed, Murphy Type, Size 7.5MM
843080	Endotracheal Tube, Uncuffed, Murphy Type, Size 8.0MM
843085	Endotracheal Tube, Uncuffed, Murphy Type, Size 8.5MM
843090	Endotracheal Tube, Uncuffed, Murphy Type, Size 9.0MM
843095	Endotracheal Tube, Uncuffed, Murphy Type, Size 9.5MM
843100	Endotracheal Tube, Uncuffed, Murphy Type, Size 10.0MM