

Declaration of Conformity

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

SRN: CN-MF-000006728

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

Product Name: Tracheal Tube

Intended Purpose: Tracheal Tube is inserted into the trachea through nose or mouth and is indicated for facilitating positive pressure ventilation and maintaining upper airway patency.

Type/ Size/ Catalogue Number: Please refer to Table 1

UMDNS Code: 14085

GMDN Code: 46967

EMDN Code: R010301, R010302

Basic UDI-DI: Please refer to Table 1

Classification (MDR, Annex VIII): **Ila, Rule 5**

Conformity Assessment Route: Quality Management System (Annex IX, Chapter I & III) +
Declaration of Conformity (Annex IV)

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

Regulation(s)

General applicable regulations: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applicable Standard(s):

EN ISO 13485:2016/A11:2021 / EN ISO 5361:2016/ EN ISO 80369-7/ EN ISO 14971:2019/
CEN ISO/TR 24971:2020/ EN ISO 20417:2021/ EN ISO 10993-1:2020/ EN ISO 10993-5:2009/
EN ISO 10993-6:2016/ EN ISO 10993-7:2008+AC:2009/ EN ISO 10993-10:2013/ EN
ISO 10993-11:2018/ EN ISO 10993-12:2012/ EN ISO 18562-1:2020/ EN ISO 18562-2:2020/
EN ISO 18562-3:2020/IEC 62366-1:2015+AMD1:2020/ SCHEER guidelines/ ISTA 2A/ ASTM
F1980-16/ MEDDEV 2.7.1 rev.4/ MDCG 2020-5/ MDCG 2020-6/ MDCG 2020-7

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

Identification number: CE0123

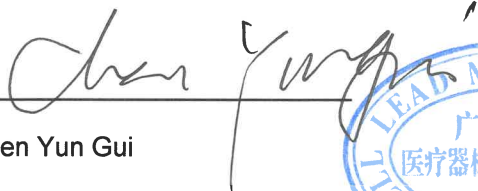
(EC) Certificate(s): G10 038814 0092 Rev. 00

Expire date of the Certificate: 2028/5/15

Start of MDR CE Marking: 2023/5/16



Signature:


Chen Yun Gui

Name:

Chen Yun Gui

Position:

Management Representative & PRRC

Place, Date of Issue: **Guangzhou, 2023-5-18**



Table1

Model	Type	Basic UDI-DI	Size	Catalogue Number	ASID BONZ REF	Type	Basic UDI-DI	Size	Catalogue Number	ASID BONZ REF
Standard Tracheal Tube	HVLP cuffed	69449327FA01A00BW	3.0	A01A01301F	840030, 841030	LP cuffed	69449327FA01A01BY	2.5	A01A01252F	/
			3.5	A01A01351F	840035, 841035			3.0	A01A01302F	
			4.0	A01A01401F	840040, 841040			3.5	A01A01352F	
			4.5	A01A01451F	840045, 841045			4.0	A01A01402F	
			5.0	A01A01501F	840050, 841050			4.5	A01A01452F	
			5.5	A01A01551F	840055, 841055			5.0	A01A01502F	
			6.0	A01A01601F	840060, 841060			5.5	A01A01552F	
			6.5	A01A01651F	840065, 841065			6.0	A01A01602F	
			7.0	A01A01701F	840070, 841070			6.5	A01A01652F	
			7.5	A01A01751F	840075, 841075			7.0	A01A01702F	
			8.0	A01A01801F	840080, 841080			7.5	A01A01752F	
			8.5	A01A01851F	840085, 841085			8.0	A01A01802F	
			9.0	A01A01901F	840090, 841090			8.5	A01A01852F	
			9.5	A01A01951F	840095, 841095			9.0	A01A01902F	
			10.0	A01A01961F	840100, 841100			9.5	A01A01952F	
			10.5	A01A01971F	/			10.0	A01A01962F	
			11.0	A01A01981F				/		
			PU cuffed	69449327FA01A02C2	3.0			A01G01304F		



Model	Type	Basic UDI-DI	Size	Catalogue Number	ASID BONZ REF	Type	Basic UDI-DI	Size	Catalogue Number	ASID BONZ REF					
			3.5	A01G01354F				2.5	A01A02253F	842025, 843025					
			4.0	A01G01404F				3.0	A01A02303F	842030, 843030					
			4.5	A01G01454F	/			3.5	A01A02353F	842035, 843035					
			5.0	A01G01504F				4.0	A01A02403F	842040, 843040					
			5.5	A01G01554F				4.5	A01A02453F	842045, 843045					
			6.0	A01G01604F				5.0	A01A02503F	842050, 843050					
			6.5	A01G01654F				5.5	A01A02553F	842055, 843055					
			7.0	A01G01704F				6.0	A01A02603F	842060, 843060					
			7.5	A01G01754F				6.5	A01A02653F	/					
			8.0	A01G01804F				7.0	A01A02703F						
			8.5	A01G01854F				7.5	A01A02753F						
			9.0	A01G01904F				8.0	A01A02803F						
			9.5	A01G01954F				8.5	A01A02853F						
			10.0	A01G01964F				9.0	A01A02903F						
		/						9.5	A01A02953F						
								10.0	A01A02963F						
								10.5	A01A02973F						
								11.0	A01A02983F						
			Oral Tracheal Tube	HVLP cuffed				69449327FA01B00C3	3.0		A01B01301F	LP cuffed	69449327FA01B01C5	3.0	A01B01302F
									3.5		A01B01351F			3.5	A01B01352F
4.0	A01B01401F	4.0			A01B01402F										
4.5	A01B01451F	4.5			A01B01452F										
5.0	A01B01501F	5.0			A01B01502F										
5.5	A01B01551F	5.5			A01B01552F										
			6.0	A01B01601F			6.0	A01B01602F							

Model	Type	Basic UDI-DI	Size	Catalogue Number	ASID BONZ REF	Type	Basic UDI-DI	Size	Catalogue Number	ASID BONZ REF
			6.5	A01B01651F				6.5	A01B01652F	
			7.0	A01B01701F				7.0	A01B01702F	
			7.5	A01B01751F				7.5	A01B01752F	
			8.0	A01B01801F				8.0	A01B01802F	
			8.5	A01B01851F				8.5	A01B01852F	
			9.0	A01B01901F				9.0	A01B01902F	
			9.5	A01B01951F				9.5	A01B01952F	
			10.0	A01B01961F				10.0	A01B01962F	
	PU cuffed	69449327FA01B02C7	3.0	A01G15304F			un- cuffed	3.0	A01B02303F	
			3.5	A01G15354F				3.5	A01B02353F	
			4.0	A01G15404F				4.0	A01B02403F	
			4.5	A01G15454F				4.5	A01B02453F	
			5.0	A01G15504F				5.0	A01B02503F	
			5.5	A01G15554F				5.5	A01B02553F	
			6.0	A01G15604F				6.0	A01B02603F	
			6.5	A01G15654F				6.5	A01B02653F	
			7.0	A01G15704F				7.0	A01B02703F	
			7.5	A01G15754F				7.5	A01B02753F	
			8.0	A01G15804F				8.0	A01B02803F	
			8.5	A01G15854F				8.5	A01B02853F	
			9.0	A01G15904F				9.0	A01B02903F	
			9.5	A01G15954F				9.5	A01B02953F	
			10.0	A01G15964F				10.0	A01B02963F	
Nasal Tracheal Tube	HVLP cuffed	69449327FA01C00C8	3.0	A01C01301F		LP cuffed	69449327FA01C01CA	3.0	A01C01302F	
			3.5	A01C01351F				3.5	A01C01352F	
			4.0	A01C01401F				4.0	A01C01402F	
			4.5	A01C01451F				4.5	A01C01452F	
			5.0	A01C01501F				5.0	A01C01502F	
			5.5	A01C01551F				5.5	A01C01552F	
			6.0	A01C01601F				6.0	A01C01602F	
			6.5	A01C01651F				6.5	A01C01652F	

Model	Type	Basic UDI-DI	Size	Catalogue Number	ASID BONZ REF	Type	Basic UDI-DI	Size	Catalogue Number	ASID BONZ REF
			7.0	A01C01701F				7.0	A01C01702F	
			7.5	A01C01751F				7.5	A01C01752F	
			8.0	A01C01801F				8.0	A01C01802F	
			8.5	A01C01851F				8.5	A01C01852F	
			9.0	A01C01901F				9.0	A01C01902F	
			9.5	A01C01951F				9.5	A01C01952F	
			10.0	A01C01961F				10.0	A01C01962F	
	PU cuffed	69449327FA01C02CC	3.0	A01G02304F		un- cuffed	69449327FA01C03CE	3.0	A01C02303F	
			3.5	A01G02354F				3.5	A01C02353F	
			4.0	A01G02404F				4.0	A01C02403F	
			4.5	A01G02454F				4.5	A01C02453F	
			5.0	A01G02504F				5.0	A01C02503F	
			5.5	A01G02554F				5.5	A01C02553F	
			6.0	A01G02604F				6.0	A01C02603F	
			6.5	A01G02654F				6.5	A01C02653F	
			7.0	A01G02704F				7.0	A01C02703F	
			7.5	A01G02754F				7.5	A01C02753F	
			8.0	A01G02804F				8.0	A01C02803F	
			8.5	A01G02854F				8.5	A01C02853F	
			9.0	A01G02904F				9.0	A01C02903F	
			9.5	A01G02954F				9.5	A01C02953F	
			10.0	A01G02964F				10.0	A01C02963F	

