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Document Nr.: WL-MDR-DOC-002-01-17/B

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
SRN:	DE-AR-000000001
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

WELL LEAD MEDICAL CO. LTD. 广州维力医疗器械股份有限公司

Classification (MDR, Annex Ⅷ): **IIa, 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 5361:2016, EN ISO 80369-7:2021, ISO 18190: 2016, EN ISO 15001:2011, EN ISO 5356-1:2015, EN ISO 13485:2016+A11:2021, EN ISO 14971:2019+A11:2021, CEN ISO/TR 24971:2020, ASTM F640-20, EN ISO 11135:2014+A1:2019, EN ISO 11138-1:2017, EN ISO 11138-2:2017, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018+A1:2021, EN ISO 11737-2:2020, EN ISO 15223-1:2021, 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 10993-12:2021, EN ISO 10993-17:2009, EN ISO 10993-18:2020, ISO/TS 21726:2019, EN ISO 18562-1:2020, EN ISO 18562-2:2020, EN ISO 18562-3:2020, IEC 62366-1:2015+AMD1:2020, ISTA 2A, ASTM F1980-21, MDCG 2020-5, MDCG 2020-6, MEDDEV 2.7.1 rev.4, MEDDEV 2.12-1 rev.8, MEDDEV 2.12-2 rev.2, MDCG 2020-7, MDCG 2020-8, SCHEER guidelines, MDCG 2018-1 rev.4, MDCG 2019-1

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Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany
Identification number:	CE0123
(EC) Certificate(s):	G10 038814 0092 Rev. 01
Expire date of the Certificate:	2028/5/15
Start of MDR CE Marking:	2023/5/16

Signature: _____

WELLEAD MEDICAL CO. LTD. 广州维力医疗器械股份有限公司

Name: Chen Yun Gui

Position: **Management Representative & PRRC**

Place, Date of Issue: **Guangzhou, 2023-12-12**

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Table1

Model	Type	Basic UDI-DI	Size	Well Lead REF	Medline-EU REF	Description
Standard Tracheal Tube	HVLP cuffed	69449327FA01A00BW	3.0	A01A01301Z	840030	Endotracheal Tube, Cuffed, Magil Type, Size 3.0MM
			3.5	A01A01351Z	840035	Endotracheal Tube, Cuffed, Magil Type, Size 3.5MM
			4.0	A01A01401Z	840040	Endotracheal Tube, Cuffed, Magil Type, Size 4.0MM
			4.5	A01A01451Z	840045	Endotracheal Tube, Cuffed, Magil Type, Size 4.5MM
			5.0	A01A01501Z	840050	Endotracheal Tube, Cuffed, Magil Type, Size 5.0MM
			5.5	A01A01551Z	840055	Endotracheal Tube, Cuffed, Magil Type, Size 5.5MM
			6.0	A01A01601Z	840060	Endotracheal Tube, Cuffed, Magil Type, Size 6.0MM
			6.5	A01A01651Z	840065	Endotracheal Tube, Cuffed, Magil Type, Size 6.5MM
			7.0	A01A01701Z	840070	Endotracheal Tube, Cuffed, Magil Type, Size 7.0MM
			7.5	A01A01751Z	840075	Endotracheal Tube, Cuffed, Magil Type, Size 7.5MM
			8.0	A01A01801Z	840080	Endotracheal Tube, Cuffed, Magil Type, Size 8.0MM
			8.5	A01A01851Z	840085	Endotracheal Tube, Cuffed, Magil Type, Size 8.5MM
			9.0	A01A01901Z	840090	Endotracheal Tube, Cuffed, Magil Type, Size 9.0MM
			9.5	A01A01951Z	840095	Endotracheal Tube, Cuffed, Magil Type, Size 9.5MM
			10.0	A01A01961Z	840100	Endotracheal Tube, Cuffed, Magil Type, Size 10.0MM
			3.0	A01A01301F	841030	Endotracheal Tube, Cuffed, Murphy Type, Size 3.0MM
			3.5	A01A01351F	841035	Endotracheal Tube, Cuffed, Murphy Type, Size 3.5MM
			4.0	A01A01401F	841040	Endotracheal Tube, Cuffed, Murphy Type, Size 4.0MM
			4.5	A01A01451F	841045	Endotracheal Tube, Cuffed, Murphy Type, Size 4.5MM
			5.0	A01A01501F	841050	Endotracheal Tube, Cuffed, Murphy Type, Size 5.0MM
			5.5	A01A01551F	841055	Endotracheal Tube, Cuffed, Murphy Type, Size 5.5MM
			6.0	A01A01601F	841060	Endotracheal Tube, Cuffed, Murphy Type, Size 6.0MM
			6.5	A01A01651F	841065	Endotracheal Tube, Cuffed, Murphy Type, Size 6.5MM
			7.0	A01A01701F	841070	Endotracheal Tube, Cuffed, Murphy Type, Size 7.0MM
			7.5	A01A01751F	841075	Endotracheal Tube, Cuffed, Murphy Type, Size 7.5MM
			8.0	A01A01801F	841080	Endotracheal Tube, Cuffed, Murphy Type, Size 8.0MM
			8.5	A01A01851F	841085	Endotracheal Tube, Cuffed, Murphy Type, Size 8.5MM
			9.0	A01A01901F	841090	Endotracheal Tube, Cuffed, Murphy Type, Size 9.0MM
			9.5	A01A01951F	841095	Endotracheal Tube, Cuffed, Murphy Type, Size 9.5MM
			10.0	A01A01961F	841100	Endotracheal Tube, Cuffed, Murphy Type, Size 10.0MM

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Model	Type	Basic UDI-DI	Size	Well Lead REF	Medline-EU REF	Description
Standard Tracheal Tube	Uncuffed	69449327FA01A03C4	2.0	A01A02203Z	842020	Endotracheal Tube, Uncuffed, Magil Type, Size 2.0MM
			2.5	A01A02253Z	842025	Endotracheal Tube, Uncuffed, Magil Type, Size 2.5MM
			3.0	A01A02303Z	842030	Endotracheal Tube, Uncuffed, Magil Type, Size 3.0MM
			3.5	A01A02353Z	842035	Endotracheal Tube, Uncuffed, Magil Type, Size 3.5MM
			4.0	A01A02403Z	842040	Endotracheal Tube, Uncuffed, Magil Type, Size 4.0MM
			4.5	A01A02453Z	842045	Endotracheal Tube, Uncuffed, Magil Type, Size 4.5MM
			5.0	A01A02503Z	842050	Endotracheal Tube, Uncuffed, Magil Type, Size 5.0MM
			5.5	A01A02553Z	842055	Endotracheal Tube, Uncuffed, Magil Type, Size 5.5MM
			6.0	A01A02603Z	842060	Endotracheal Tube, Uncuffed, Magil Type, Size 6.0MM
			2.0	A01A02203F	843020	Endotracheal Tube, Uncuffed, Murphy Type, Size 2.0MM
			2.5	A01A02253F	843025	Endotracheal Tube, Uncuffed, Murphy Type, Size 2.5MM
			3.0	A01A02303F	843030	Endotracheal Tube, Uncuffed, Murphy Type, Size 3.0MM
			3.5	A01A02353F	843035	Endotracheal Tube, Uncuffed, Murphy Type, Size 3.5MM
			4.0	A01A02403F	843040	Endotracheal Tube, Uncuffed, Murphy Type, Size 4.0MM
			4.5	A01A02453F	843045	Endotracheal Tube, Uncuffed, Murphy Type, Size 4.5MM
			5.0	A01A02503F	843050	Endotracheal Tube, Uncuffed, Murphy Type, Size 5.0MM
			5.5	A01A02553F	843055	Endotracheal Tube, Uncuffed, Murphy Type, Size 5.5MM
			6.0	A01A02603F	843060	Endotracheal Tube, Uncuffed, Murphy Type, Size 6.0MM

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