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Document Nr.: WL-MDR-DOC-030-01-17/B

Declaration of Conformity

Manufacturer:	**Well Lead Medical Co., Ltd.** C-4 Jinhu Industrial Estate, Hualong 511434 Panyu, Guangzhou, People's 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 Kit
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 13485:2016+A11:2021, EN ISO 14971:2019+A11:2021, CEN ISO/TR 24971:2020, EN ISO 5361:2016, EN ISO 80369-7:2021, ASTM F640-20, EN ISO 14644 Series, 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 F1980-16, MDCG 2020-5, MDCG 2020-6, MEDDEV 2.7.1 rev.4, SCHEER guidelines

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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. 02
Expire date of the Certificate:	2028/5/15
Start of MDR CE Marking:	2024/9/14

Signature: Chen Yun Gui

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, 2026-02-03**

Add：C-4＃Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, P.R. China
Tel：+86 20 84758878
Web: http://www.wellead.com/

Table1

Model	Type	Basic UDI-DI	Size	Wellead REF	Medline REF	DESCRIPTION
Tracheal Tube Kit	Cuffed, HVLP	69449327FA01Z00FT	5.0mm	A01A05501F	845050A	Endotracheal Tube Cuffed, Murphy 5.0MM, with Stylet and 10ml Syringe
			5.5mm	A01A05551F	845055A	Endotracheal Tube Cuffed, Murphy 5.5MM, with Stylet and 10ml Syringe
			6.0mm	A01A05601F	845060A	Endotracheal Tube Cuffed, Murphy 6.0MM, with Stylet and 10ml Syringe
			6.5mm	A01A05651F	845065A	Endotracheal Tube Cuffed, Murphy 6.5MM, with Stylet and 10ml Syringe
			7.0mm	A01A05701F	845070A	Endotracheal Tube Cuffed, Murphy 7.0MM, with Stylet and 10ml Syringe
			7.5mm	A01A05751F	845075A	Endotracheal Tube Cuffed, Murphy 7.5MM, with Stylet and 10ml Syringe
			8.0mm	A01A05801F	845080A	Endotracheal Tube Cuffed, Murphy 8.0MM, with Stylet and 10ml Syringe
			8.5mm	A01A05851F	845085A	Endotracheal Tube Cuffed, Murphy 8.5MM, with Stylet and 10ml Syringe
			9.0mm	A01A05901F	845090A	Endotracheal Tube Cuffed, Murphy 9.0MM, with Stylet and 10ml Syringe
Reinforced Tracheal Tube Kit	Cuffed, HVLP	69449327FA01Z12G2	3.5mm	A01E03301F	849035AM	Reinforced ET Tube, Cuffed, Murphy, Size 3.5MM, Curved, with Curved Stylet
			4.0mm	A01E03351F	849040AM	Reinforced ET Tube, Cuffed, Murphy, Size 4.0MM, Curved, with Curved Stylet
			4.5mm	A01E03401F	849045AM	Reinforced ET Tube, Cuffed, Murphy, Size 4.5MM, Curved, with Curved Stylet
			5.0mm	A01E03451F	849050AM	Reinforced ET Tube, Cuffed, Murphy, Size 5.0MM, Curved, with Curved Stylet
			5.5mm	A01E03501F	849055AM	Reinforced ET Tube, Cuffed, Murphy, Size 5.5MM, Curved, with Curved Stylet
			6.0mm	A01E03551F	849060AM	Reinforced ET Tube, Cuffed, Murphy, Size 6.0MM, Curved, with Curved Stylet

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Reinforced Tracheal Tube Kit	Cuffed, HVLP	69449327FA01Z12G2	6.5mm	A01E03601F	849065AM	Reinforced ET Tube, Cuffed, Murphy, Size 6.5MM, Curved, with Curved Stylet
			7.0mm	A01E03651F	849070AM	Reinforced ET Tube, Cuffed, Murphy, Size 7.0MM, Curved, with Curved Stylet
			7.5mm	A01E03701F	849075AM	Reinforced ET Tube, Cuffed, Murphy, Size 7.5MM, Curved, with Curved Stylet
			8.0mm	A01E03751F	849080AM	Reinforced ET Tube, Cuffed, Murphy, Size 8.0MM, Curved, with Curved Stylet
			8.5mm	A01E03801F	849085AM	Reinforced ET Tube, Cuffed, Murphy, Size 8.5MM, Curved, with Curved Stylet
			9.0mm	A01E03851F	849090AM	Reinforced ET Tube, Cuffed, Murphy, Size 9.0MM, Curved, with Curved Stylet
	Uncuffed	69449327FA01Z14G6	3.5mm	A01E04353F	849635AM	Reinforced ET Tube, Magill without cuff, with Stylet, 3.5mm
			4.0mm	A01E04403F	849640AM	Reinforced ET Tube, Magill without cuff, with Stylet, 4.0mm
			4.5mm	A01E04453F	849645AM	Reinforced ET Tube, Magill without cuff, with Stylet, 4.5mm
			5.0mm	A01E04503F	849650AM	Reinforced ET Tube, Magill without cuff, with Stylet, 5.0mm
			5.5mm	A01E04553F	849655AM	Reinforced ET Tube, Magill without cuff, with Stylet, 5.5mm
			6.0mm	A01E04603F	849660AM	Reinforced ET Tube, Magill without cuff, with Stylet, 6.0mm
			6.5mm	A01E04653F	849665AM	Reinforced ET Tube, Magill without cuff, with Stylet, 6.5mm

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