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Document Nr.: WL-MDR-DOC-021-01-10/A

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:	Reinforced 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:	46569
EMDN Code:	R01030102, R01030202
Basic UDI-DI:	Please refer to Table 1

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

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

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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:	2024/9/14

Signature: _____

Name: Chen Yun Gui

Position: **Management Representative & PRRC**

Place, Date of Issue: **Guangzhou, 2024-9-14**

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Table1

Model	Basic UDI-DI	Type	Size (mm)	Wellead REF	Intersurgical PART NUMBER	Description
Reinforced Tracheal Tube	69449327FA01E00CJ	Cuffed, HVLP	4.5	A01E01451F	9060045	INTERTUBE TRACHEAL TUBE, REINFORCED CUFFED 4.5MM
			5.0	A01E01501F	9060050	INTERTUBE TRACHEAL TUBE, REINFORCED CUFFED 5MM
			5.5	A01E01551F	9060055	INTERTUBE TRACHEAL TUBE, REINFORCED CUFFED 5.5MM
			6.0	A01E01601F	9060060	INTERTUBE TRACHEAL TUBE, REINFORCED CUFFED 6MM
			6.5	A01E01651F	9060065	INTERTUBE TRACHEAL TUBE, REINFORCED CUFFED, 6.5MM
			7.0	A01E01701F	9060070	INTERTUBE TRACHEAL TUBE, REINFORCED CUFFED 7MM
			7.5	A01E01751F	9060075	INTERTUBE TRACHEAL TUBE, REINFORCED CUFFED 7.5MM
			8.0	A01E01801F	9060080	INTERTUBE TRACHEAL TUBE, REINFORCED CUFFED, 8MM
			8.5	A01E01851F	9060085	INTERTUBE TRACHEAL TUBE, REINFORCED CUFFED, 8.5MM
			9.0	A01E01901F	9060090	INTERTUBE TRACHEAL TUBE, REINFORCED CUFFED, 9MM
			9.5	A01E01951F	9060095	INTERTUBE TRACHEAL TUBE, REINFORCED CUFFED, 9.5MM
			10.0	A01E01961F	9060100	INTERTUBE TRACHEAL TUBE, REINFORCED CUFFED, 10MM

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