wellead 维力

Document Nr.: WL-MDR-DOC-021-01-17/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

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

wellead 维力

Document Nr.: WL-MDR-DOC-021-01-17/A

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**

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

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

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

Table1

Type	Basic UDI-DI	Size	Wellead REF	Medline REF	DESCRIPTION
Cuffed, HVLP	6944932 7FA01E 00CJ	3.5mm	A01E01351F	849035A	Reinforced ET Tube, Cuffed, Murphy, Size 3.5mm, Curved
		4.0mm	A01E01401F	849040A	Reinforced ET Tube, Cuffed, Murphy, Size 4.0mm, Curved
		4.5mm	A01E01451F	849045A	Reinforced ET Tube, Cuffed, Murphy, Size 4.5mm, Curved
		5.0mm	A01E01501F	849050A	Reinforced ET Tube, Cuffed, Murphy, Size 5.0mm, Curved
		5.5mm	A01E01551F	849055A	Reinforced ET Tube, Cuffed, Murphy, Size 5.5mm, Curved
		6.0mm	A01E01601F	849060A	Reinforced ET Tube, Cuffed, Murphy, Size 6.0mm, Curved
		6.5mm	A01E01651F	849065A	Reinforced ET Tube, Cuffed, Murphy, Size 6.5mm, Curved
		7.0mm	A01E01701F	849070A	Reinforced ET Tube, Cuffed, Murphy, Size 7.0mm, Curved
		7.5mm	A01E01751F	849075A	Reinforced ET Tube, Cuffed, Murphy, Size 7.5mm, Curved
		8.0mm	A01E01801F	849080A	Reinforced ET Tube, Cuffed, Murphy, Size 8.0mm, Curved
		8.5mm	A01E01851F	849085A	Reinforced ET Tube, Cuffed, Murphy, Size 8.5mm, Curved
		9.0mm	A01E01901F	849090A	Reinforced ET Tube, Cuffed, Murphy, Size 9.0mm, Curved
		3.5mm	A01A01351Z	849535A	Reinforced ET Tube, Curved, Magill with cuff, 3.5mm
		4.0mm	A01A01401Z	849540A	Reinforced ET Tube, Curved, Magill with cuff, 4.0mm
		4.5mm	A01A01451Z	849545A	Reinforced ET Tube, Curved, Magill with cuff, 4.5mm
		5.0mm	A01A01501Z	849550A	Reinforced ET Tube, Curved, Magill with cuff, 5.0mm
		5.5mm	A01A01551Z	849555A	Reinforced ET Tube, Curved, Magill with cuff, 5.5mm
		6.0mm	A01A01601Z	849560A	Reinforced ET Tube, Curved, Magill with cuff, 6.0mm
		6.5mm	A01A01651Z	849565A	Reinforced ET Tube, Curved, Magill with cuff, 6.5mm
		7.0mm	A01A01701Z	849570A	Reinforced ET Tube, Curved, Magill with cuff, 7.0mm
		7.5mm	A01A01751Z	849575A	Reinforced ET Tube, Curved, Magill with cuff, 7.5mm
		8.0mm	A01A01801Z	849580A	Reinforced ET Tube, Curved, Magill with cuff, 8.0mm
		8.5mm	A01A01851Z	849585A	Reinforced ET Tube, Curved, Magill with cuff, 8.5mm
		9.0mm	A01A01901Z	849590A	Reinforced ET Tube, Curved, Magill with cuff, 9.0mm
Uncuffed	6944932 7FA01E 03CQ	3.0mm	A01E02303F	849630A	Reinforced ET Tube, Curved, Magill without cuff, 3.0mm
		3.5mm	A01E02353F	849635A	Reinforced ET Tube, Curved, Magill without cuff, 3.5mm
		4.0mm	A01E02403F	849640A	Reinforced ET Tube, Curved, Magill without cuff, 4.0mm
		4.5mm	A01E02453F	849645A	Reinforced ET Tube, Curved, Magill without cuff, 4.5mm
		5.0mm	A01E02503F	849650A	Reinforced ET Tube, Curved, Magill without cuff, 5.0mm
		5.5mm	A01E02553F	849655A	Reinforced ET Tube, Curved, Magill without cuff, 5.5mm
		6.0mm	A01E02603F	849660A	Reinforced ET Tube, Curved, Magill without cuff, 6.0mm
		6.5mm	A01E02653F	849665A	Reinforced ET Tube, Curved, Magill without cuff, 6.5mm



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