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)** Eiffestrasse 80, 20537 Hamburg, GERMANY
SRN:	DE-AR-000000001
Product Name:	Endobronchial Tube
Intended Purpose:	The Endobronchial Tube is usually inserted into the bronchus and trachea through mouth, and are intended for one-lung ventilation during thoracic surgery or for anesthesia during pulmonary surgery.
Type/ Size/ Catalogue Number:	Please refer to Table 1
UMDNS Code:	15322
GMDN Code:	31328
EMDN Code:	R010401, R010402
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 above mentioned products 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):
ISO 16628:2022, ISO 18190:2016, EN ISO 13485:2016+A11:2021, EN ISO 14971:2019, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-7:2008+A1:2022, EN ISO 10993-17:2009, EN ISO 10993-18:2020, EN ISO 10993-10:2013, EN ISO 10993-12:2021, EN ISO 10993-23:2021, EN ISO 18562-1:2020, EN ISO 18562-2:2020, EN ISO 18562-3:2020, EN ISO 18562-4:2020, EN ISO 11135:2014+A1:2019, EN ISO 11737-1:2018, EN ISO 11737-2:2020, EN ISO 15223-1:2021, CEN ISO/TR 24971:2020 , EN ISO 11138-1:2017, EN ISO 11138-2:2017, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN 556-1:2001/AC:2006, EN 868-5: 2018, ASTM F1929-15, ASTM F1886-16, EN ISO 20417:2021, ISO/TS 21726:2019, 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.

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:	2023/12/12

Place, Date of Issue:

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, 2024-3-15**

Table1 Catalogue Number

Model	Type	Basic UDI-DI	Size	Wellead REF	Medline REF	DESCRIPTION
Endobronchial Tube	Left	69449327FA03A01CE	28Fr	A03A01281F	847028ALZ	Endobronchial Tube, Left 28FR, with Adapter or Suction Catheters
			32Fr	A03A01321F	847032ALZ	Endobronchial Tube, Left 32FR, with Adapter or Suction Catheters
			35Fr	A03A01351F	847035ALZ	Endobronchial Tube, Left 35FR, with Adapter or Suction Catheters
			37Fr	A03A01371F	847037ALZ	Endobronchial Tube, Left 37FR, with Adapter or Suction Catheters
			39Fr	A03A01391F	847039ALZ	Endobronchial Tube, Left 39FR, with Adapter or Suction Catheters
			41Fr	A03A01411F	847041ALZ	Endobronchial Tube, Left 41FR, with Adapter or Suction Catheters
	Right	69449327FA03A02CG	28Fr	A03A02281F	847028ARZ	Endobronchial Tube, Right 28FR, with Adapter or Suction Catheters
			32Fr	A03A02321F	847032ARZ	Endobronchial Tube, Right 32FR, with Adapter or Suction Catheters
			35Fr	A03A02351F	847035ARZ	Endobronchial Tube, Right 35FR, with Adapter or Suction Catheters
			37Fr	A03A02371F	847037ARZ	Endobronchial Tube, Right 37FR, with Adapter or Suction Catheters
			39Fr	A03A02391F	847039ARZ	Endobronchial Tube, Right 39FR, with Adapter or Suction Catheters
			41Fr	A03A02411F	847041ARZ	Endobronchial Tube, Right 41FR, with Adapter or Suction Catheters

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