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Document Nr.: WL-MDR-DOC-041-01-01/A

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 Blocker Tube
Intended Purpose:	Endobronchial Blocker Tube is usually inserted into the bronchus and trachea through mouth, and is intended for one-lung ventilation during thoracic surgery or during pulmonary surgery.
Type/ Size/ Catalogue Number:	Please refer to Table 1
UMDNS Code:	17860
GMDN Code:	17827
EMDN Code:	R010499
Basic UDI-DI:	Please refer to Table 1

Classification (MDR, Annex Ⅷ): **IIa, Rule 5**

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

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):
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.

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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:	2023/12/12

Table1 Catalogue Number

Type	Size	Basic UDI-DI	Wellead REF	Unoquip REF	Description
PU cuff	5 Fr	69449327FA03E00CY	A03D01051F	65110518	Endobronchial Blocker Tube, Fr.5
	7 Fr		A03D01071F	65110718	Endobronchial Blocker Tube, Fr.7
	9 Fr		A03D01091F	65110918	Endobronchial Blocker Tube, Fr.9

Place, Date of Issue:

Signature:

Name: Chen Yun Gui

Position: **Management Representative & PRRC**

Place, Date of Issue: **Guangzhou, 2026/02/03**

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

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