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Document Nr.: WL-MDR-DOC-005-01/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:	Oropharyngeal Airway
Intended Purpose:	The oropharyngeal airway is used to create an airway path between the oral cavity and the back wall of the pharynx. It prevents the tongue and/or epiglottis of anesthetized or unconscious patients from falling back to the posterior pharynx, so as not to obstruct air flow.
Type/ Size/ Catalogue Number:	Please refer to Table 1
UMDNS Code:	10059
GMDN Code:	42424
EMDN Code:	R010102
Basic UDI-DI:	Guedel Airway 69449327FA06B01D8 Berman Airway 69449327FA06B02DA

Classification (MDR, Annex Ⅷ): Is, 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):

ISO 11712:2009 / ISO 18190:2016 / EN ISO 5364:2016 / EN ISO 13485:2016+A11:2021 / EN ISO 14971:2019 / CEN ISO/TR 24971:2020/ EN ISO 14644-1:2015/ EN ISO 14644-2:2015/ EN ISO 14644-3:2019/ EN ISO 14644-4:2022/ EN ISO 14644-5:2004/ EN ISO 14644-7:2004/ EN ISO 14644-8:2022/ EN ISO 14644-9:2022/ EN ISO 14644-10:2022/ ISO 14644-12:2018/ EN ISO 14644-13:2017/ EN ISO 14644-14:2016/ EN ISO 14644-15:2017/ EN ISO 14644-16:2019/ EN ISO 14644-17:2021/ EN 17141: 2022/ EN ISO 11135:2014+A1:2019/ EN ISO 11737-1:2018+A1:2021/ EN ISO 11737-2:2020/ EN ISO 10993-1:2020/ EN ISO 10993-5:2009/ EN ISO 10993-10:2013/ EN ISO 20417:2021/ EN ISO 15223-1:2021/ ISO/TS 21726:2019/ EN 15986:2011/ EN ISO 18562-

1:2020/ EN ISO 18562-2:2020/ EN ISO 18562-3:2020 / EN ISO 18562-4:2020 / IEC 62366-1:2015+AMD1:2020/ SCHEER guidelines / ISTA 2A/ EN 868-2:2017/ ASTM F1980-21 / MEDDEV 2.7.1 rev.4/ MDCG 2020-5/ MDCG 2020-6/ MDCG 2020-7

Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany
Identification number:	CE0123
(EC) Certificate(s):	G11 038814 0093 Rev. 00
Expire date of the Certificate:	2028/12/5
Start of MDR CE Marking:	2023/12/6

Signature:

Name: Chen Yun Gui

Position: **Management Representative & PRRC**

Place, Date of Issue: **Guangzhou, 2023-12-6**

Add: C-4 # Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, P.R. China
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Table1

Model	Size	Catalogue Number	ASID BONZ REF	DESCRIPTION
Guedel Airway	4cm	A06B020410	830001M	Guedel Airway, Size 000# 4cm
	5cm	A06B020510	830002M	Guedel Airway, Size 00# 5cm
	6cm	A06B020610	830003M	Guedel Airway, Size 0# 6cm
	7cm	A06B020710	830010M	Guedel Airway, Size 1# 7cm
	8cm	A06B020810	830020M	Guedel Airway, Size 2# 8cm
	9cm	A06B020910	830030M	Guedel Airway, Size 3# 9cm
	10cm	A06B021010	830040M	Guedel Airway, Size 4# 10cm
	11cm	A06B021110	830050M	Guedel Airway, Size 5# 11cm
	12cm	A06B021210	830060M	Guedel Airway, Size 6# 12cm

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

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