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Document Nr.: WL-MDR-DOC-037-01-17/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)** Eiffestrasse 80, 20537 Hamburg, GERMANY
SRN:	DE-AR-000000001
Product Name:	Oxygen Catheter
Intended Purpose:	The Oxygen Catheter is intended for direct administration of oxygen via nasopharyngeal rout.
Type/ Size/ Catalogue Number:	Please refer to Table 1
GMDN Code:	12855, 35201
EMDN Code:	R03010203
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 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 14971:2019+A11:2021, EN ISO 13485:2016+A11:2021, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-6-2016, EN ISO 10993-10:2023, EN ISO 10993-11:2018, EN ISO 10993-12:2021, ISO 10993-18:2020+AMD 1:2022, EN ISO 10993-23:2021, EN ISO 15223-1:2021, EN ISO 11135:2014+A1:2019, EN ISO 11737-1:2018+A1:2021, EN ISO 11737-2:2020, CEN ISO/TR 24971:2020, ISO 18190:2016, EN ISO 80369-1:2018, Meddev 2.7.1 rev.4, MDCG 2020-5, MDCG 2020-6, EN 62366-1:2015+A1:2020, IEC/TR 62366-2:2016, EN ISO 10993-17:2009, ISO/TS 21726:2019, ISO/TS 10993-19:2020, EN ISO 20417:2021, ISTA 2A, EN ISO 11607-1:2020+A11:2022, EN ISO 11607-2:2020+A11:2022, EN ISO 11138-1:2017, EN ISO 11138-2:2017, EN ISO 10993-7:2008+A1:2022, EN ISO 14644 Series, EN 17141: 2022, SCHEER guidelines, Regulation (EC) No 1907/2006-REACH, EN 15986:2011, EN 556-1:2001+AC:2006, EN 556-2:2015, EN 868-5:2018, ASTM F1886-16, ASTM F88-15, ASTM F1929-15, EN ISO 5356 Series, EN ISO 5359:2014+A1:2017, EN ISO 21969:2009, EN ISO 18562-1:2020, EN ISO 18562-2:2020, EN ISO 18562-3:2020, EN ISO 18562-4:2020.

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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:	2023/12/12

Signature:



Name: Chen Yun Gui

Position: **Management Representative & PRRC**

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

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

Table 1

Type	Basic UDI-DI	Size	Wellead REF	Medline REF	DESCRIPTION
Fixed compress, Male connector	69449327F R01B00JY	8Fr	R01B03081Y	820608A	Oxygen Catheter, 8Fr
		10Fr	R01B03101Y	820610A	Oxygen Catheter, 10Fr
		12Fr	R01B03121Y	820612A	Oxygen Catheter, 12Fr
		14Fr	R01B03141Y	820614A	Oxygen Catheter, 14Fr

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