wellead 维力

Document Nr.: WL-DOC-082/C

# Declaration of Conformity

| | |
|---|---|
| Manufacturer: | **Well Lead Medical Co., Ltd.**<br>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)<br>Eiffestrasse 80, 20537 Hamburg, GERMANY |
| Product Name: | Male External Catheter |
| Type: | Type I, Type II, Type III |
| Size: | 25mm, 28mm, 29mm, 30mm, 32mm, 36mm, 41mm |
| Catalogue No. | Refer to Annex I |
| UMDNS Code: | 10765 |
| EMDN Code: | U070201 |
| CND Code: | U070201 |
| Basic UDI-DI: | 69449327FF03A00ED |

Classification (MDR, Annex Ⅷ): **I (Non-sterile), Rule 1**

Conformity Assessment Route: **Technical Documentation (Annex Ⅱ and Annex 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 15223-1: 2021/ EN ISO 20417:2021/ EN ISO 10993-1:2020/ EN ISO 10993-5:2009/ EN ISO 10993-10:2013/ ASTM F1980-16/ ISTA 2A/ IEC 62366-1:2015+AMD 1:2020/ EN ISO 14644-1:2015/ EN ISO 14644-2:2015/ MEDDEV 2.7.1 rev.4/ MDCG 2020-5/ MDCG 2020-6/ MDCG 2020-7

Signature: _____

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

Name: Chen Yun Gui

Position: **Management Representative**

Place, Date of Issue: **Guangzhou, 2022-02-28**

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

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**Annex I Catalogue No.**

| Model | Size | Cat. No. |
|---|---|---|
| Type Ⅰ | 25mm | F03A012510/F03A012520 |
| | 28mm | F03A012810/ F03A012820 |
| | 29mm | F03A012910/ F03A012920 |
| | 30mm | F03A013010/ F03A013020 |
| | 32mm | F03A013210/ F03A013220 |
| | 36mm | F03A013610/ F03A013620 |
| | 41mm | F03A014110/ F03A014120 |
| Type Ⅱ | 25mm | F03A022510/ F03A022520 |
| | 28mm | F03A022810/ F03A022820 |
| | 29mm | F03A022910/ F03A022920 |
| | 30mm | F03A023010/ F03A023020 |
| | 32mm | F03A023210/ F03A023220 |
| | 36mm | F03A023610/ F03A023620 |
| | 41mm | F03A024110/ F03A024120 |
| Type Ⅲ | 25mm | F03A032510/ F03A032520 |
| | 28mm | F03A032810/ F03A032820 |
| | 29mm | F03A032910/ F03A032920 |
| | 30mm | F03A033010/ F03A033020 |
| | 32mm | F03A033210/ F03A033220 |
| | 36mm | F03A033610/ F03A033620 |
| | 41mm | F03A034110/ F03A034120 |

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

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