

## 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

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.

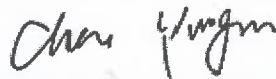
### Regulation(s)

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:



Name:

Chen Yun Gui

Position:

**Management Representative**

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



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 |

