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Document Nr.: WL-MDR-DOC-038-02/A

# Declaration of Conformity

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|---|---|
| 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: | Spigot |
| Intended Purpose: | It is used to inserted into the drainage lumen of foley catheter to temperately stop the urine drainage. |
| EMDN Code: | A070501 |
| Basic UDI-DI: | 69449327FF05A00ET |

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 20696:2018/ EN ISO 14971:2019/ CEN ISO/TR 24971:2020/ EN ISO 15223-1:2021/ EN ISO 20417:2021/ EN ISO 10993-1:2020/ IEC 62366-1:2015+AMD1:2020/ SCHEER guidelines/ ISTA 2A/ ASTM F1980-16/ MEDDEV 2.7.1 rev.4/ MDCG 2020-5/ MDCG 2020-6

Table1 Catalogue Number

| Product Name | Size | Catalogue Number | ASID BONZ REF | DESCRIPTION |
|---|---|---|---|---|
| Spigot | Universal | F05A010110 | 647010-U | Spigot-U, Bulk, unsterile |

Signature:

Name: Chen Yun Gui

Position: **Management Representative**

Place, Date of Issue: **Guangzhou, 2022-12-22**

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