wellead 维力

Document Nr.: WL-MDR-DOC-019/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: | Nelaton Catheter |
| Intended Purpose: | Nelaton catheter is inserted into the bladder through urethra and are indicated for intermittent urine drainage. |
| Type/ Size/ Catalogue Number: | Please refer to Table 1 |
| UMDNS Code: | 10734 |
| GMDN Code: | 34930 |
| EMDN Code: | U01010502 |
| Basic UDI-DI: | 69449327FF01D00EE |

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.

Confidential

## 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 20417:2021/ EN ISO 10993-1:2020/ EN ISO 10993-5:2009/ EN ISO 10993-7:2008+AC:2009/ EN ISO 10993-10:2013/ EN ISO 10993-12:2012/ 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/ MDCG 2020-7

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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. 00 |
| Expire date of the Certificate: | 2028/5/15 |
| Start of MDR CE Marking: | 2023/5/16 |

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

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Table1 Catalogue Number

| Type | Size | Catalogue Number |
|---|---|---|
| Female | 6Fr | F01D02061F |
| | 8 Fr | F01D02081F |
| | 10Fr | F01D02101F |
| | 12Fr | F01D02121F |
| | 14 Fr | F01D02141F |
| | 16Fr | F01D02161F |
| | 18Fr | F01D02181F |
| | 20Fr | F01D02201F |
| | 22Fr | F01D02221F |
| | 24Fr | F01D02241F |
| Standard | 6Fr | F01D01061F |
| | 8 Fr | F01D01081F |
| | 10Fr | F01D01101F |
| | 12Fr | F01D01121F |
| | 14 Fr | F01D01141F |
| | 16Fr | F01D01161F |
| | 18Fr | F01D01181F |
| | 20Fr | F01D01201F |
| | 22Fr | F01D01221F |
| | 24Fr | F01D01241F |
| Tiemann Tip | 10Fr | F01D03101F |
| | 12Fr | F01D03121F |
| | 14 Fr | F01D03141F |
| | 16Fr | F01D03161F |
| | 18Fr | F01D03181F |
| | 20Fr | F01D03201F |
| | 22Fr | F01D03221F |

Confidential

Place, Date of Issue:

Signature:

Name: Chen Yun Gui

Position: **Management Representative & PRRC**

Place, Date of Issue: **Guangzhou, 2023-5-18**

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

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