

## 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)**  
Eiffestrase 80, 20537 Hamburg, GERMANY

SRN: DE-AR-000000001

Product Name: All Silicone Foley Catheter

Intended Purpose: All Silicone Foley Catheter is intended to be used by trained person or trained medical staff for drainage and/or irrigation of the patient bladder by inserting the catheter into the vesical cavity of the bladder through the urethra.

Type/ Size/ Catalogue Number: Please refer to Table 1

UMDNS Code: 10720

GMDN Code: 34917

EMDN Code: U010299

Basic UDI-DI: Please refer to Table 1

Classification (MDR, Annex VIII ): **IIb, 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 products mentioned above 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.

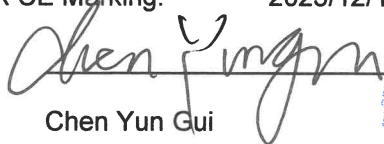
### Applicable Standard(s):

EN ISO 20696:2018, EN ISO 13485:2016+A11:2021, EN ISO 14971:2019, CEN ISO/TR 24971:2020, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN ISO 14644-3:2019, EN ISO 14644-4:2001, EN ISO 14644-5:2004, EN ISO 14644-7:2004, EN ISO 14644-8:2013, EN ISO 14644-9:2012, EN ISO 14644-10:2013, EN ISO 14644-13:2017, EN ISO 14644-14:2016, EN ISO 14644-16:2019, EN ISO 14644-17:2021, EN ISO 11135:2014+A1:2019, EN ISO 11138-1:2017, EN ISO 11138-2:2017, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018, EN ISO 11737-2:2020, EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 10993-1:2020, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-6:2016, EN ISO 10993-7:2008+AC:2009, EN ISO 10993-10:2013, EN ISO 10993-11:2018, EN ISO 10993-12:2021, EN ISO 10993-17:2009, EN ISO 10993-18:2020, ISO/TS 10993-19:2020, ISO/TS

21726:2019, IEC 62366-1:2015+AMD1:2020, ISTA 2A, ASTM F1980-21, MEDDEV 2.7.1 revision 4, SCHEER guidelines

Notified Body: BSI Group The Netherlands B.V.  
Identification number: CE2797  
(EC) Certificate(s): MDR 801167 R000  
Expire date of the Certificate: 2028/12/13  
Start of MDR CE Marking: 2023/12/14

Signature:



Name: Chen Yun Gui

Position: **Management Representative & PRRC**



Place, Date of Issue: **Guangzhou, 2023-12-14**

Table1 Catalogue Number



| Model                       | Type             | Size | Balloon Volume | REF        | Basic UDI-DI      |
|-----------------------------|------------------|------|----------------|------------|-------------------|
| All Silicone Foley Catheter | 2-way, Pediatric | 6Fr  | 1.5ml          | F01B040601 | 69449327FF01B01E6 |
|                             |                  | 6Fr  | 3ml            | F01B040602 |                   |
|                             |                  | 8Fr  | 3ml            | F01B040802 |                   |
|                             |                  | 8Fr  | 3-5ml          | F01B040803 |                   |
|                             |                  | 10Fr | 3ml            | F01B041002 |                   |
|                             |                  | 10Fr | 3-5ml          | F01B041003 |                   |
|                             |                  | 10Fr | 5ml            | F01B041004 |                   |
|                             | 2-way, Female    | 12Fr | 5ml            | F01B031204 | 69449327FF01B01E8 |
|                             |                  | 12Fr | 5-10ml         | F01B031205 |                   |
|                             |                  | 12Fr | 10ml           | F01B031207 |                   |
|                             |                  | 12Fr | 5-15ml         | F01B031206 |                   |
|                             |                  | 12Fr | 15ml           | F01B031208 |                   |
|                             |                  | 12Fr | 20ml           | F01B031220 |                   |
|                             |                  | 14Fr | 5ml            | F01B031404 |                   |
|                             |                  | 14Fr | 5-10ml         | F01B031405 |                   |
|                             |                  | 14Fr | 10ml           | F01B031407 |                   |
|                             |                  | 14Fr | 5-15ml         | F01B031406 |                   |
|                             |                  | 14Fr | 15ml           | F01B031408 |                   |
|                             |                  | 14Fr | 20ml           | F01B031420 |                   |
|                             |                  | 16Fr | 5ml            | F01B031604 |                   |
|                             |                  | 16Fr | 5-10ml         | F01B031605 |                   |
|                             |                  | 16Fr | 10ml           | F01B031607 |                   |
|                             |                  | 16Fr | 5-15ml         | F01B031606 |                   |
|                             |                  | 16Fr | 15ml           | F01B031608 |                   |
|                             |                  | 16Fr | 20ml           | F01B031620 |                   |
|                             |                  | 16Fr | 30ml           | F01B031610 |                   |
|                             |                  | 18Fr | 5ml            | F01B031804 |                   |
|                             |                  | 18Fr | 5-10ml         | F01B031805 |                   |
|                             |                  | 18Fr | 10ml           | F01B031807 |                   |
|                             |                  | 18Fr | 5-15ml         | F01B031806 |                   |
|                             |                  | 18Fr | 15ml           | F01B031808 |                   |
|                             |                  | 18Fr | 20ml           | F01B031820 |                   |
|                             |                  | 18Fr | 30ml           | F01B031810 |                   |
|                             |                  | 20Fr | 5ml            | F01B032004 |                   |
|                             |                  | 20Fr | 5-10ml         | F01B032005 |                   |
|                             |                  | 20Fr | 10ml           | F01B032007 |                   |
|                             |                  | 20Fr | 5-15ml         | F01B032006 |                   |
|                             |                  | 20Fr | 15ml           | F01B032008 |                   |
|                             |                  | 20Fr | 20ml           | F01B032020 |                   |
|                             |                  | 20Fr | 30ml           | F01B032010 |                   |
|                             |                  | 22Fr | 5ml            | F01B032204 |                   |
|                             |                  | 22Fr | 5-10ml         | F01B032205 |                   |
|                             |                  | 22Fr | 10ml           | F01B032207 |                   |
|                             |                  | 22Fr | 5-15ml         | F01B032206 |                   |
|                             |                  | 22Fr | 15ml           | F01B032208 |                   |
|                             |                  | 22Fr | 20ml           | F01B032220 |                   |
|                             |                  | 22Fr | 30ml           | F01B032210 |                   |
|                             |                  | 24Fr | 5ml            | F01B032404 |                   |
|                             |                  | 24Fr | 5-10ml         | F01B032405 |                   |
|                             |                  | 24Fr | 10ml           | F01B032407 |                   |
|                             |                  | 24Fr | 5-15ml         | F01B032406 |                   |
|                             |                  | 24Fr | 15ml           | F01B032408 |                   |



| Model                       | Type            | Size | Balloon Volume | REF        | Basic UDI-DI      |
|-----------------------------|-----------------|------|----------------|------------|-------------------|
| All Silicone Foley Catheter | 2-way, Female   | 24Fr | 20ml           | F01B032420 | 69449327FF01B01E8 |
|                             |                 | 24Fr | 30ml           | F01B032410 |                   |
|                             |                 | 26Fr | 5ml            | F01B032604 |                   |
|                             |                 | 26Fr | 5-10ml         | F01B032605 |                   |
|                             |                 | 26Fr | 10ml           | F01B032607 |                   |
|                             |                 | 26Fr | 5-15ml         | F01B032606 |                   |
|                             |                 | 26Fr | 15ml           | F01B032608 |                   |
|                             |                 | 26Fr | 20ml           | F01B032620 |                   |
|                             |                 | 26Fr | 30ml           | F01B032610 |                   |
|                             | 2-way, Standard | 12Fr | 5ml            | F01B011204 | 69449327FF01B01E4 |
|                             |                 | 12Fr | 5-10ml         | F01B011205 |                   |
|                             |                 | 12Fr | 10ml           | F01B011207 |                   |
|                             |                 | 12Fr | 5-15ml         | F01B011206 |                   |
|                             |                 | 12Fr | 15ml           | F01B011208 |                   |
|                             |                 | 12Fr | 20ml           | F01B011220 |                   |
|                             |                 | 14Fr | 5mL            | F01B011404 |                   |
|                             |                 | 14Fr | 5-10mL         | F01B011405 |                   |
|                             |                 | 14Fr | 10mL           | F01B011407 |                   |
|                             |                 | 14Fr | 5-15mL         | F01B011406 |                   |
|                             |                 | 14Fr | 15mL           | F01B011408 |                   |
|                             |                 | 14Fr | 20mL           | F01B011420 |                   |
|                             |                 | 16Fr | 5mL            | F01B011604 |                   |
|                             |                 | 16Fr | 5-10mL         | F01B011605 |                   |
|                             |                 | 16Fr | 10mL           | F01B011607 |                   |
|                             |                 | 16Fr | 5-15mL         | F01B011606 |                   |
|                             |                 | 16Fr | 15mL           | F01B011608 |                   |
|                             |                 | 16Fr | 20mL           | F01B011620 |                   |
|                             |                 | 16Fr | 30mL           | F01B011610 |                   |
|                             |                 | 18Fr | 5mL            | F01B011804 |                   |
|                             |                 | 18Fr | 5-10mL         | F01B011805 |                   |
|                             |                 | 18Fr | 10mL           | F01B011807 |                   |
|                             |                 | 18Fr | 5-15mL         | F01B011806 |                   |
|                             |                 | 18Fr | 15mL           | F01B011808 |                   |
|                             |                 | 18Fr | 20mL           | F01B011820 |                   |
|                             |                 | 18Fr | 30mL           | F01B011810 |                   |
|                             |                 | 20Fr | 5mL            | F01B012004 |                   |
|                             |                 | 20Fr | 5-10mL         | F01B012005 |                   |
|                             |                 | 20Fr | 10mL           | F01B012007 |                   |
|                             |                 | 20Fr | 5-15mL         | F01B012006 |                   |
|                             |                 | 20Fr | 15mL           | F01B012008 |                   |
|                             |                 | 20Fr | 20mL           | F01B012020 |                   |
|                             |                 | 20Fr | 30mL           | F01B012010 |                   |
|                             |                 | 22Fr | 5mL            | F01B012204 |                   |
|                             |                 | 22Fr | 5-10mL         | F01B012205 |                   |
|                             |                 | 22Fr | 10mL           | F01B012207 |                   |
|                             |                 | 22Fr | 5-15mL         | F01B012206 |                   |
|                             |                 | 22Fr | 15mL           | F01B012208 |                   |
|                             |                 | 22Fr | 20mL           | F01B012220 |                   |
|                             |                 | 22Fr | 30mL           | F01B012210 |                   |
|                             |                 | 24Fr | 5mL            | F01B012404 |                   |
|                             |                 | 24Fr | 5-10mL         | F01B012405 |                   |
|                             |                 | 24Fr | 10mL           | F01B012407 |                   |
|                             |                 | 24Fr | 5-15mL         | F01B012406 |                   |
|                             |                 | 24Fr | 15mL           | F01B012408 |                   |
|                             |                 | 24Fr | 20mL           | F01B012420 |                   |

Add: C-4 # Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, P.R. China  
Tel: +86 20 84758878  
Web: <https://www.wellead.com/>



| Model                       | Type            | Size | Balloon Volume | REF        | Basic UDI-DI      |
|-----------------------------|-----------------|------|----------------|------------|-------------------|
| All Silicone Foley Catheter | 2-way, Standard | 24Fr | 30mL           | F01B012410 | 69449327FF01B01E4 |
|                             |                 | 26Fr | 5mL            | F01B012604 |                   |
|                             |                 | 26Fr | 5-10mL         | F01B012605 |                   |
|                             |                 | 26Fr | 10mL           | F01B012607 |                   |
|                             |                 | 26Fr | 5-15mL         | F01B012606 |                   |
|                             |                 | 26Fr | 15mL           | F01B012608 |                   |
|                             |                 | 26Fr | 20mL           | F01B012620 |                   |
|                             |                 | 26Fr | 30mL           | F01B012610 |                   |
|                             | 2-way, Open Tip | 8Fr  | 3ml            | U07B050802 | 69449327FF01B03EA |
|                             |                 | 10Fr | 3ml            | U07B051002 |                   |
|                             |                 | 10Fr | 3-5ml          | U07B051003 |                   |
|                             |                 | 10Fr | 5ml            | U07B051004 |                   |
|                             |                 | 12Fr | 5ml            | U07B061204 |                   |
|                             |                 | 12Fr | 5-10ml         | U07B061205 |                   |
|                             |                 | 12Fr | 10ml           | U07B061207 |                   |
|                             |                 | 12Fr | 5-15ml         | U07B061206 |                   |
|                             |                 | 12Fr | 15ml           | U07B061208 |                   |
|                             |                 | 12Fr | 20ml           | U07B061220 |                   |
|                             |                 | 14Fr | 5ml            | U07B061404 |                   |
|                             |                 | 14Fr | 5-10ml         | U07B061405 |                   |
|                             |                 | 14Fr | 10ml           | U07B061407 |                   |
|                             |                 | 14Fr | 5-15ml         | U07B061406 |                   |
|                             |                 | 14Fr | 15ml           | U07B061408 |                   |
|                             |                 | 14Fr | 20ml           | U07B061420 |                   |
|                             |                 | 16Fr | 5ml            | U07B061604 |                   |
|                             |                 | 16Fr | 5-10ml         | U07B061605 |                   |
|                             |                 | 16Fr | 10ml           | U07B061607 |                   |
|                             |                 | 16Fr | 5-15ml         | U07B061606 |                   |
|                             |                 | 16Fr | 15ml           | U07B061608 |                   |
|                             |                 | 16Fr | 20ml           | U07B061620 |                   |
|                             |                 | 16Fr | 30ml           | U07B061610 |                   |
|                             |                 | 18Fr | 5ml            | U07B061804 |                   |
|                             |                 | 18Fr | 5-10ml         | U07B061805 |                   |
|                             |                 | 18Fr | 10ml           | U07B061807 |                   |
|                             |                 | 18Fr | 5-15ml         | U07B061806 |                   |
|                             |                 | 18Fr | 15ml           | U07B061808 |                   |
|                             |                 | 18Fr | 20ml           | U07B061820 |                   |
|                             |                 | 18Fr | 30ml           | U07B061810 |                   |
|                             |                 | 20Fr | 5ml            | U07B062004 |                   |
|                             |                 | 20Fr | 5-10ml         | U07B062005 |                   |
|                             |                 | 20Fr | 10ml           | U07B062007 |                   |
|                             |                 | 20Fr | 5-15ml         | U07B062006 |                   |
|                             |                 | 20Fr | 15ml           | U07B062008 |                   |
|                             |                 | 20Fr | 20ml           | U07B062020 |                   |
|                             |                 | 20Fr | 30ml           | U07B062010 |                   |
|                             |                 | 22Fr | 5ml            | U07B062204 |                   |
|                             |                 | 22Fr | 5-10ml         | U07B062205 |                   |
|                             |                 | 22Fr | 10ml           | U07B062207 |                   |
|                             |                 | 22Fr | 5-15ml         | U07B062206 |                   |
|                             |                 | 22Fr | 15ml           | U07B062208 |                   |
|                             |                 | 22Fr | 20ml           | U07B062220 |                   |
|                             |                 | 22Fr | 30ml           | U07B062210 |                   |
|                             |                 | 24Fr | 5ml            | U07B062404 |                   |
|                             |                 | 24Fr | 5-10ml         | U07B062405 |                   |
|                             |                 | 24Fr | 10ml           | U07B062407 |                   |

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| Model                       | Type              | Size | Balloon Volume | REF        | Basic UDI-DI      |
|-----------------------------|-------------------|------|----------------|------------|-------------------|
| All Silicone Foley Catheter | 2-way, Open Tip   | 24Fr | 5-15ml         | U07B062406 | 69449327FF01B03EA |
|                             |                   | 24Fr | 15ml           | U07B062408 |                   |
|                             |                   | 24Fr | 20ml           | U07B062420 |                   |
|                             |                   | 24Fr | 30ml           | U07B062410 |                   |
|                             |                   | 26Fr | 5ml            | U07B062604 |                   |
|                             |                   | 26Fr | 5-10ml         | U07B062605 |                   |
|                             |                   | 26Fr | 10ml           | U07B062607 |                   |
|                             |                   | 26Fr | 5-15ml         | U07B062606 |                   |
|                             |                   | 26Fr | 15ml           | U07B062608 |                   |
|                             |                   | 26Fr | 20ml           | U07B062620 |                   |
|                             |                   | 26Fr | 30ml           | U07B062610 |                   |
|                             | 2-way, Tiemann    | 12Fr | 5ml            | F01B051204 | 69449327FF01B05EE |
|                             |                   | 12Fr | 10ml           | F01B051207 |                   |
|                             |                   | 12Fr | 15ml           | F01B051208 |                   |
|                             |                   | 14Fr | 5ml            | F01B051404 |                   |
|                             |                   | 14Fr | 10ml           | F01B051405 |                   |
|                             |                   | 14Fr | 15ml           | F01B051406 |                   |
|                             |                   | 16Fr | 5ml            | F01B051604 |                   |
|                             |                   | 16Fr | 10ml           | F01B051607 |                   |
|                             |                   | 16Fr | 15ml           | F01B051608 |                   |
|                             |                   | 16Fr | 30ml           | F01B051610 |                   |
|                             |                   | 18Fr | 10ml           | F01B051807 |                   |
|                             |                   | 18Fr | 15ml           | F01B051808 |                   |
|                             |                   | 18Fr | 30ml           | F01B051810 |                   |
|                             |                   | 20Fr | 10ml           | F01B052007 |                   |
|                             |                   | 20Fr | 15ml           | F01B052008 |                   |
|                             |                   | 20Fr | 30ml           | F01B052010 |                   |
|                             |                   | 22Fr | 10ml           | F01B052207 |                   |
|                             |                   | 22Fr | 15ml           | F01B052208 |                   |
|                             |                   | 22Fr | 30ml           | F01B052210 |                   |
|                             |                   | 24Fr | 10ml           | F01B052407 |                   |
|                             |                   | 24Fr | 15ml           | F01B282408 |                   |
|                             |                   | 24Fr | 30ml           | F01B052410 |                   |
|                             |                   | 26Fr | 10ml           | F01B282607 |                   |
|                             |                   | 26Fr | 15ml           | F01B282608 |                   |
|                             |                   | 26Fr | 30ml           | F01B052610 |                   |
|                             | 2-way, Couvelaire | 12Fr | 20ml           | F01B071220 | 69449327FF01B06EG |
|                             |                   | 14Fr | 20ml           | F01B071420 |                   |
|                             |                   | 16Fr | 20ml           | F01B071620 |                   |
|                             |                   | 16Fr | 30ml           | F01B071610 |                   |
|                             |                   | 18Fr | 20ml           | F01B071820 |                   |
|                             |                   | 18Fr | 30ml           | F01B071810 |                   |
|                             |                   | 18Fr | 30-50ml        | F01B071812 |                   |
|                             |                   | 20Fr | 20ml           | F01B072020 |                   |
|                             |                   | 20Fr | 30ml           | F01B072010 |                   |
|                             |                   | 20Fr | 30-50ml        | F01B072012 |                   |
|                             |                   | 22Fr | 20ml           | F01B072220 |                   |
|                             |                   | 22Fr | 30ml           | F01B072210 |                   |
|                             |                   | 22Fr | 30-50ml        | F01B072212 |                   |
|                             |                   | 24Fr | 20ml           | F01B072420 |                   |
|                             |                   | 24Fr | 30ml           | F01B072410 |                   |
|                             |                   | 24Fr | 30-50ml        | F01B072412 |                   |
|                             | 2-way, Dufour     | 12Fr | 20ml           | F01B091220 | 69449327FF01B07EJ |
|                             |                   | 14Fr | 20ml           | F01B091420 |                   |
|                             |                   | 16Fr | 20ml           | F01B091620 |                   |

| Model                       | Type              | Size | Balloon Volume | REF        | Basic UDI-DI      |
|-----------------------------|-------------------|------|----------------|------------|-------------------|
| All Silicone Foley Catheter | 2-way, Dufour     | 16Fr | 30ml           | F01B091610 | 69449327FF01B07EJ |
|                             |                   | 18Fr | 20ml           | F01B091820 |                   |
|                             |                   | 18Fr | 30ml           | F01B091810 |                   |
|                             |                   | 18Fr | 30-50ml        | F01B091812 |                   |
|                             |                   | 20Fr | 20ml           | F01B092020 |                   |
|                             |                   | 20Fr | 30ml           | F01B092010 |                   |
|                             |                   | 20Fr | 30-50ml        | F01B092012 |                   |
|                             |                   | 22Fr | 20ml           | F01B092220 |                   |
|                             |                   | 22Fr | 30ml           | F01B092210 |                   |
|                             |                   | 22Fr | 30-50ml        | F01B092212 |                   |
|                             |                   | 24Fr | 20ml           | F01B092420 |                   |
|                             |                   | 24Fr | 30ml           | F01B092410 |                   |
|                             |                   | 24Fr | 30-50ml        | F01B092412 |                   |
|                             | 2-way, Mercier    | 12Fr | 20ml           | F01B111220 | 69449327FF01B08EL |
|                             |                   | 14Fr | 20ml           | F01B111420 |                   |
|                             |                   | 16Fr | 20ml           | F01B111620 |                   |
|                             |                   | 16Fr | 30ml           | F01B111610 |                   |
|                             |                   | 18Fr | 20ml           | F01B111820 |                   |
|                             |                   | 18Fr | 30ml           | F01B111810 |                   |
|                             |                   | 18Fr | 30-50ml        | F01B111812 |                   |
|                             |                   | 20Fr | 20ml           | F01B112020 |                   |
|                             |                   | 20Fr | 30ml           | F01B112010 |                   |
|                             |                   | 20Fr | 30-50ml        | F01B112012 |                   |
|                             |                   | 22Fr | 20ml           | F01B112220 |                   |
|                             |                   | 22Fr | 30ml           | F01B112210 |                   |
|                             |                   | 22Fr | 30-50ml        | F01B112212 |                   |
|                             |                   | 24Fr | 20ml           | F01B112420 |                   |
|                             |                   | 24Fr | 30ml           | F01B112410 |                   |
|                             |                   | 24Fr | 30-50ml        | F01B112412 |                   |
|                             | 3-way, Couvelaire | 16Fr | 20ml           | F01B081620 | 69449327FF01B11E9 |
|                             |                   | 16Fr | 30ml           | F01B081610 |                   |
|                             |                   | 18Fr | 20ml           | F01B081820 |                   |
|                             |                   | 18Fr | 30ml           | F01B081810 |                   |
|                             |                   | 18Fr | 30-50ml        | F01B081812 |                   |
|                             |                   | 20Fr | 20ml           | F01B082020 |                   |
|                             |                   | 20Fr | 30ml           | F01B082010 |                   |
|                             |                   | 20Fr | 30-50ml        | F01B082012 |                   |
|                             |                   | 22Fr | 20ml           | F01B082220 |                   |
|                             |                   | 22Fr | 30ml           | F01B082210 |                   |
|                             |                   | 22Fr | 30-50ml        | F01B082212 |                   |
|                             |                   | 24Fr | 20ml           | F01B082420 |                   |
|                             |                   | 24Fr | 30ml           | F01B082410 |                   |
|                             |                   | 24Fr | 30-50ml        | F01B082412 |                   |
|                             | 3-way, Dufour     | 16Fr | 20ml           | F01B101620 | 69449327FF01B12EB |
|                             |                   | 16Fr | 30ml           | F01B101610 |                   |
|                             |                   | 18Fr | 20ml           | F01B101820 |                   |
|                             |                   | 18Fr | 30ml           | F01B101810 |                   |
|                             |                   | 18Fr | 30-50ml        | F01B101812 |                   |
|                             |                   | 20Fr | 20ml           | F01B102020 |                   |
|                             |                   | 20Fr | 30ml           | F01B102010 |                   |
|                             |                   | 20Fr | 30-50ml        | F01B102012 |                   |
|                             |                   | 22Fr | 20ml           | F01B102220 |                   |
|                             |                   | 22Fr | 30ml           | F01B102210 |                   |
|                             |                   | 22Fr | 30-50ml        | F01B102212 |                   |
|                             |                   | 24Fr | 20ml           | F01B102420 |                   |

Add: C-4 # Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, P.R. China  
Tel: +86 20 84758878  
Web: <https://www.wellead.com/>

| Model                                               | Type             | Size | Balloon Volume | REF        | Basic UDI-DI      |
|-----------------------------------------------------|------------------|------|----------------|------------|-------------------|
| All Silicone Foley Catheter                         | 3-way, Dufour    | 24Fr | 30ml           | F01B102410 | 69449327FF01B12EB |
|                                                     |                  | 24Fr | 30-50ml        | F01B102412 |                   |
|                                                     | 3-way, Mercier   | 16Fr | 20ml           | F01B121620 | 69449327FF01B13ED |
|                                                     |                  | 16Fr | 30ml           | F01B121610 |                   |
|                                                     |                  | 18Fr | 20ml           | F01B121820 |                   |
|                                                     |                  | 18Fr | 30ml           | F01B121810 |                   |
|                                                     |                  | 18Fr | 30-50ml        | F01B121812 |                   |
|                                                     |                  | 20Fr | 20ml           | F01B122020 |                   |
|                                                     |                  | 20Fr | 30ml           | F01B122010 |                   |
|                                                     |                  | 20Fr | 30-50ml        | F01B122012 |                   |
|                                                     |                  | 22Fr | 20ml           | F01B122220 |                   |
|                                                     |                  | 22Fr | 30ml           | F01B122210 |                   |
|                                                     |                  | 22Fr | 30-50ml        | F01B122212 |                   |
|                                                     |                  | 24Fr | 20ml           | F01B122420 |                   |
|                                                     |                  | 24Fr | 30ml           | F01B122410 |                   |
|                                                     |                  | 24Fr | 30-50ml        | F01B122412 |                   |
|                                                     | 3-way, Standard  | 16Fr | 5-10ml         | F01B061605 | 69449327FF01B09EN |
|                                                     |                  | 16Fr | 10ml           | F01B061607 |                   |
|                                                     |                  | 16Fr | 5-15ml         | F01B061606 |                   |
|                                                     |                  | 16Fr | 15ml           | F01B061608 |                   |
|                                                     |                  | 16Fr | 30ml           | F01B061610 |                   |
|                                                     |                  | 18Fr | 5-10ml         | F01B061805 |                   |
|                                                     |                  | 18Fr | 10ml           | F01B061807 |                   |
|                                                     |                  | 18Fr | 5-15ml         | F01B061806 |                   |
|                                                     |                  | 18Fr | 15ml           | F01B061808 |                   |
|                                                     |                  | 18Fr | 30ml           | F01B061810 |                   |
|                                                     |                  | 18Fr | 30-50ml        | F01B061812 |                   |
|                                                     |                  | 20Fr | 5-10ml         | F01B062005 |                   |
|                                                     |                  | 20Fr | 10ml           | F01B062007 |                   |
|                                                     |                  | 20Fr | 5-15ml         | F01B062006 |                   |
|                                                     |                  | 20Fr | 15ml           | F01B062008 |                   |
|                                                     |                  | 20Fr | 30ml           | F01B062010 |                   |
|                                                     |                  | 20Fr | 30-50ml        | F01B062012 |                   |
|                                                     |                  | 22Fr | 5-10ml         | F01B062205 |                   |
|                                                     |                  | 22Fr | 10ml           | F01B062207 |                   |
|                                                     |                  | 22Fr | 5-15ml         | F01B062206 |                   |
|                                                     |                  | 22Fr | 15ml           | F01B062208 |                   |
|                                                     |                  | 22Fr | 30ml           | F01B062210 |                   |
|                                                     |                  | 22Fr | 30-50ml        | F01B062212 |                   |
|                                                     |                  | 24Fr | 5-10ml         | F01B062405 |                   |
|                                                     |                  | 24Fr | 10ml           | F01B062407 |                   |
|                                                     |                  | 24Fr | 5-15ml         | F01B062406 |                   |
|                                                     |                  | 24Fr | 15ml           | F01B062408 |                   |
|                                                     |                  | 24Fr | 30ml           | F01B062410 |                   |
|                                                     |                  | 24Fr | 30-50ml        | F01B062412 |                   |
|                                                     |                  | 26Fr | 5-10ml         | F01B062605 |                   |
|                                                     |                  | 26Fr | 10ml           | F01B062607 |                   |
|                                                     |                  | 26Fr | 5-15ml         | F01B062606 |                   |
|                                                     |                  | 26Fr | 15ml           | F01B062608 |                   |
|                                                     |                  | 26Fr | 30ml           | F01B062610 |                   |
|                                                     |                  | 26Fr | 30-50ml        | F01B062612 |                   |
| All Silicone Foley Catheter with Integrated Balloon | 2-way, Pediatric | 10Fr | 3ml            | F01B211002 | 69449327FF01B14EF |
|                                                     |                  | 10Fr | 5ml            | F01B181004 |                   |
|                                                     | 2-way, Standard  | 12Fr | 5ml            | F01B211204 | 69449327FF01B15EH |
|                                                     |                  | 12Fr | 5-10ml         | F01B211205 |                   |

Add: C-4 # Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, P.R. China  
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Web: <https://www.wellead.com/>

| Model                                               | Type            | Size | Balloon Volume | REF        | Basic UDI-DI      |
|-----------------------------------------------------|-----------------|------|----------------|------------|-------------------|
| All Silicone Foley Catheter with Integrated Balloon | 2-way, Standard | 12Fr | 10ml           | F01B211207 | 69449327FF01B15EH |
|                                                     |                 | 14Fr | 5ml            | F01B211404 |                   |
|                                                     |                 | 14Fr | 5-10ml         | F01B211405 |                   |
|                                                     |                 | 14Fr | 10ml           | F01B211407 |                   |
|                                                     |                 | 16Fr | 5ml            | F01B211604 |                   |
|                                                     |                 | 16Fr | 5-10ml         | F01B211605 |                   |
|                                                     |                 | 16Fr | 10ml           | F01B211607 |                   |
|                                                     |                 | 18Fr | 5ml            | F01B211804 |                   |
|                                                     |                 | 18Fr | 5-10ml         | F01B211805 |                   |
|                                                     |                 | 18Fr | 10ml           | F01B211807 |                   |
|                                                     |                 | 20Fr | 5ml            | F01B212004 |                   |
|                                                     |                 | 20Fr | 5-10ml         | F01B212005 |                   |
|                                                     |                 | 20Fr | 10ml           | F01B212007 |                   |
|                                                     |                 | 22Fr | 5ml            | F01B212204 |                   |
|                                                     |                 | 22Fr | 5-10ml         | F01B212205 |                   |
|                                                     |                 | 22Fr | 10ml           | F01B212207 |                   |
|                                                     |                 | 24Fr | 5ml            | F01B212404 |                   |
|                                                     |                 | 24Fr | 5-10ml         | F01B222405 |                   |
|                                                     |                 | 24Fr | 10ml           | F01B212407 |                   |
|                                                     | 2-way, Tiemann  | 12Fr | 5ml            | F01B311204 | 69449327FF01B17EM |
|                                                     |                 | 12Fr | 5-10ml         | F01B221205 |                   |
|                                                     |                 | 12Fr | 10ml           | F01B221227 |                   |
|                                                     |                 | 14Fr | 5ml            | F01B311404 |                   |
|                                                     |                 | 14Fr | 5-10ml         | F01B221405 |                   |
|                                                     |                 | 14Fr | 10ml           | F01B221427 |                   |
|                                                     |                 | 16Fr | 5ml            | F01B311604 |                   |
|                                                     |                 | 16Fr | 5-10ml         | F01B221605 |                   |
|                                                     |                 | 16Fr | 10ml           | F01B221627 |                   |
|                                                     |                 | 18Fr | 5ml            | F01B311804 |                   |
|                                                     |                 | 18Fr | 5-10ml         | F01B221805 |                   |
|                                                     |                 | 18Fr | 10ml           | F01B221827 |                   |
|                                                     |                 | 20Fr | 5ml            | F01B312004 |                   |
|                                                     |                 | 20Fr | 5-10ml         | F01B222005 |                   |
|                                                     |                 | 20Fr | 10ml           | F01B222027 |                   |
|                                                     |                 | 22Fr | 5ml            | F01B312204 |                   |
|                                                     |                 | 22Fr | 5-10ml         | F01B222205 |                   |
|                                                     |                 | 22Fr | 10ml           | F01B222227 |                   |
|                                                     |                 | 24Fr | 5ml            | F01B312404 |                   |
|                                                     |                 | 24Fr | 5-10ml         | F01B222405 |                   |
|                                                     |                 | 24Fr | 10ml           | F01B222427 |                   |

