

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

SRN: DE-AR-000000001

Product Name: Urine Bag

Intended Purpose: The Urine Bag is used for the collection and temporary storage of urine. It is intended to be used with an indwelling catheter in incontinent patients, cannot urinate normally, or are requiring continuous bladder drainage.

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

UMDNS Code: 11301

GMDN Code: 58923

EMDN Code: A06030301

Basic UDI-DI: Please refer to Table 1

Classification (MDR, Annex VIII ): **Is, Rule 1**

Conformity Assessment Route: Quality Management System (Annex IX, Chapter I & III and section 4) + 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 8669-2:1997, ISO 13485:2016+A11:2021, EN ISO 14971:2019+A11:2021, CEN ISO/TR 24971:2020, EN ISO 11135:2014+A1:2019, EN ISO 11138-1:2017, EN ISO 11138-2:2017, EN 556-1:2001/AC:2006, EN 556-2:2015, EN ISO 11737-1:2018+A1:2021, EN ISO 11737-2:2020, EN ISO 10993-7:2008+A1:2022, EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 10993-1:2020, EN ISO 10993-5:2009, ISO 10993-10:2021, EN ISO 10993-12:2021, IEC 62366-1:2015+AMD1:2020, IEC/TR 62366-2:2016, ASTM D4332-13, ASTM D4169-14, ASTM D7386-16, EN ISO 4180:2019, ASTM F1929-15, ASTM F88/F88M-09, EN ISO 11607-1:2020, EN ISO 11607-2:2020, ASTM F1980-21, MDCG 2020-5, MDCG 2020-6, MEDDEV 2.7.1 revision 4, MEDDEV 2.12/1 rev.8, MEDDEV 2.12-2 rev 2 (2012), MDCG 2020-7, MDCG 2020-8, MDCG 2018-1 Rev.4, MDCG 2019-1, SCHEER guidelines

Notified Body: BSI Group The Netherlands B.V.  
Identification number: CE 2797  
(EC) Certificate(s): MDR 776669 R000  
Expire date of the Certificate: 2027-12-18  
Start of MDR CE Marking: 2023-12-14

Signature:   
Name: Chen Yun Gui  
Position: Management Representative & PRRC  
Place, Date of Issue: Guangzhou, 2025.09.22



Table1 Catalogue Number

| Product name | Model  | Basic UDI-DI      | Unoquip REF | Product Description (size, type)  |
|--------------|--|-------------------|-------------|---|
| Urine Bag    | Exchange Bag   | 69449327FF04C01EY | 15840101    | Change bag for Q500 Plus 2L, T-Tap  |
|              |  |                   | 15820101    | Change bag for Q500 Plus 2L, Use-Once outlet                                    |
|              |  |                   | 15830101    | Change bag for Q500 Plus 3.5L, Use-Once outlet                                  |
|              | Drainage Bag (Type B)  | 69449327FF04A02EQ | 38016218    | Bed Bag CSB Q4 Sterile, NRV, T-Tap, Clamp, Hanger, 2L, 120cm                    |
|              |  |                   | 38016318    | Bed Bag CSB Q4 Sterile, NRV, T-Tap, Clamp, 2L, 120cm                            |
|              |  |                   | 38016418    | Bed Bag CSB Q4 Sterile, NRV, T-Tap, Clamp, 2L, 100cm                            |
|              |  |                   | 48011018    | Q4000 TUR Irrigation Bag, 4L125cm, no Pumpball                                  |
|              |  |                   | 48011118    | Q4000 TUR Irrigation Bag,4L125cm, Pumpball, 2clamps                             |
|              |  |                   | 41014918    | Bed Bag CSB Q6 Sterile, NRV, T-Tap, Clamp, Hanger, Drip chamber, 2L,120cm       |
|              |  |                   | 41004918    | Bed Bag CSB Q5 Sterile, NRV, T-Tap, Clamp. Hanger, Short drip chamber, 2L,110cm |
|              |  |                   | 38012618    | Night Bag QE4 Sterile, NRV, T-Tap not foldable Clamp, 2L,120cm                  |
|              |  |                   | 38016718    | Bed Bag CSB Q4 Sterile, NRV, Lever-Tap, Clamp, 2L, 100cm                        |
|              | Leg Bag  | 69449327FF04D01F5 | 23510118    | Leg Bag HHC Sterile, 350ml, 30cm, T-Tap, Soft backing, Needle-free port         |
|              |  |                   | 23510218    | Leg Bag HHC Sterile,350ml, 9cm,T-Tap, Soft backing, Needle-free port            |
|              |  |                   | 25010118    | Leg Bag HHC Sterile,500ml, 9cm, T-Tap, No backing, Needle-free port             |
|              |  |                   | 25010218    | Leg Bag HHC Sterile,500ml,30cm,T-Tap, No backing, Needle-free port              |
|              |  |                   | 25010318    | Leg Bag HHC Sterile,500ml, 30cm, T-Tap, Soft backing, Needle-free port          |
|              |  |                   | 25010418    | Leg Bag HHC Sterile,500ml, 9cm, T-Tap, Soft backing, Needle-free port           |
|              |  |                   | 25010518    | Leg Bag HHC Sterile,500ml,30cm, Lever-tap No backing, Needle-free port          |
|              |  |                   | 25010618    | Leg Bag HHC Sterile, 500ml, 9cm, Lever-tap, No backing, Needle-free port        |
|              |  |                   | 25010718    | Leg Bag HHC Sterile, 500ml, 30cm, Lever-tap, Soft backing, Needle-free port     |
|              |  |                   | 25010818    | Leg Bag HHC Sterile, 500ml, 9cm, Lever-tap, Soft backing, Needle-free port      |
|              |  |                   | 27510918    | Leg Bag HHC Sterile, 700ml, 50cm, T-tap, Soft backing, Cut-to-fit               |
|              |  |                   | 27510118    | Leg Bag HHC Sterile, 750ml, 10cm, T-Tap, Soft backing                           |
|              |  |                   | 27510218    | Leg Bag HHC Sterile,750ml, 30cm, T-Tap, Soft backing, Needle-free port          |
|              |  |                   | 27510318    | Leg Bag HHC Sterile,750ml, 9cm, T-Tap, Soft backing, Needle-free port           |
|              |  |                   | 27510418    | Leg Bag HHC Sterile,750ml, 9cm,Lever-tap,Soft backing, Needle-free port         |
| 27510518     | Leg Bag HHC Sterile,750ml, 30cm, Lever-tap, Soft backing, Needle-free port |                   |             |   |