

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: Latex Foley Catheter

Intended Purpose: Latex Foley Catheter is inserted into the bladder through urethra and are indicated for routine urine drainage or for routine post-operative drainage and irrigation bladder.

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.

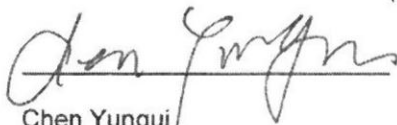
Applicable Standard(s):

EN ISO 20696:2018, EN ISO 13485:2016+A11:2021, EN ISO 14971:2019, CEN ISO/TR 24971:2020, ISO 80369-7: 2021, ISO 2004:2017, 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, MDCG 2020-5, MDCG 2020-6, 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 Yungui

Position: **Management Representative & PRRC**



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

Table1 Catalogue Number

Basic UDI-DI	Type	Size	REF
69449327FF01A01DZ	2-way, Pediatric	6Fr, 3mL	F01A060602
		8Fr, 3mL	F01A060802
		8Fr, 3-5mL	F01A060803
		8Fr, 5mL	F01A060804
		10Fr, 3mL	F01A061002
		10Fr, 3-5mL	F01A061003
		10Fr, 5mL	F01A061004
69449327FF01A00DX	2-way, standard	12Fr, 5mL	F01A021204
		12Fr, 5-10mL	F01A021205
		12Fr, 10mL	F01A021207
		12Fr, 5-15mL	F01A021206
		12Fr, 15mL	F01A021208
		12Fr, 15-30mL	F01A021209
		12Fr, 30mL	F01A021210
		14Fr, 5mL	F01A021404
		14Fr, 5-10mL	F01A021405
		14Fr, 10mL	F01A021407
		14Fr, 5-15mL	F01A021406
		14Fr, 15mL	F01A021408
		14Fr, 15-30mL	F01A021409
		14Fr, 30mL	F01A021410
		16Fr, 5mL	F01A021604
		16Fr, 5-10mL	F01A021605
		16Fr, 10mL	F01A021607
		16Fr, 5-15mL	F01A021606
		16Fr, 15mL	F01A021608
		16Fr, 30mL	F01A021610
		16Fr, 30-50mL	F01A021612
		18Fr, 5mL	F01A021804
		18Fr, 5-10mL	F01A021805
		18Fr, 10mL	F01A021807
		18Fr, 5-15mL	F01A021806
		18Fr, 15mL	F01A021808
		18Fr, 30mL	F01A021810
		18Fr, 30-50mL	F01A021812
		20Fr, 5mL	F01A022004
		20Fr, 5-10mL	F01A022005
		20Fr, 10mL	F01A022007
		20Fr, 5-15mL	F01A022006
		20Fr, 15mL	F01A022008
		20Fr, 30mL	F01A022010
		20Fr, 30-50mL	F01A022012
		22Fr, 5mL	F01A022204
		22Fr, 5-10mL	F01A022205
		22Fr, 10mL	F01A022207
		22Fr, 5-15mL	F01A022206
		22Fr, 15mL	F01A022208
		22Fr, 30mL	F01A022210



Basic UDI-DI	Type	Size	REF
69449327FF01A00DX	2-way, standard	22Fr, 30-50mL	F01A022212
		24Fr, 5-10mL	F01A022405
		24Fr, 10mL	F01A022407
		24Fr, 5-15mL	F01A022406
		24Fr, 15mL	F01A022408
		24Fr, 30mL	F01A022410
		24Fr, 30-50mL	F01A022412
		26Fr, 5-10mL	F01A022605
		26Fr, 10mL	F01A022607
		26Fr, 5-15mL	F01A022606
		26Fr, 15mL	F01A022608
		26Fr, 30mL	F01A022610
		26Fr, 30-50mL	F01A022612
		28Fr, 5-10mL	F01A022805
		28Fr, 10mL	F01A022807
		28Fr, 5-15mL	F01A022806
		28Fr, 15mL	F01A022808
		28Fr, 30mL	F01A022810
		28Fr, 30-50mL	F01A022812
		30Fr, 5-10mL	F01A023005
		30Fr, 10mL	F01A023007
		30Fr, 5-15mL	F01A023006
		30Fr, 15mL	F01A023008
		30Fr, 30mL	F01A023010
		30Fr, 30-50mL	F01A023012
	2-way, Female	12Fr, 5mL	F01A041204
		12Fr, 5-10mL	F01A041205
		12Fr, 10mL	F01A041207
		12Fr, 5-15mL	F01A041206
		12Fr, 15mL	F01A041208
		12Fr, 15-30mL	F01A041209
		12Fr, 30mL	F01A041210
		14Fr, 5mL	F01A041404
		14Fr, 5-10mL	F01A041405
		14Fr, 10mL	F01A041407
		14Fr, 5-15mL	F01A041406
		14Fr, 15mL	F01A041408
		14Fr, 15-30mL	F01A041409
		14Fr, 30mL	F01A041410
		16Fr, 5mL	F01A041604
		16Fr, 5-10mL	F01A041605
		16Fr, 10mL	F01A041607
		16Fr, 5-15mL	F01A041606
		16Fr, 15mL	F01A041608
		16Fr, 30mL	F01A041610
		16Fr, 30-50mL	F01A041612
		18Fr, 5mL	F01A041804
		18Fr, 5-10mL	F01A041805
		18Fr, 10mL	F01A041807



Basic UDI-DI	Type	Size	REF
69449327FF01A00DX	2-way, Female	18Fr, 5-15mL	F01A041806
		18Fr, 15mL	F01A041808
		18Fr, 30mL	F01A041810
		18Fr, 30-50mL	F01A041812
		20Fr, 5mL	F01A042004
		20Fr, 5-10mL	F01A042005
		20Fr, 10mL	F01A042007
		20Fr, 5-15mL	F01A042006
		20Fr, 15mL	F01A042008
		20Fr, 30mL	F01A042010
		20Fr, 30-50mL	F01A042012
		22Fr, 5mL	F01A042204
		22Fr, 5-10mL	F01A042205
		22Fr, 10mL	F01A042207
		22Fr, 5-15mL	F01A042206
		22Fr, 15mL	F01A042208
		22Fr, 30mL	F01A042210
		22Fr, 30-50mL	F01A042212
		24Fr, 5-10mL	F01A042405
		24Fr, 10mL	F01A042407
		24Fr, 5-15mL	F01A042406
		24Fr, 15mL	F01A042408
		24Fr, 30mL	F01A042410
		24Fr, 30-50mL	F01A042412
		26Fr, 10mL	F01A042607
		26Fr, 5-15mL	F01A042606
		26Fr, 15mL	F01A042608
		26Fr, 30mL	F01A042610
		26Fr, 30-50mL	F01A042612
	2-way, Tiemann	12Fr, 5mL	F01A081204
		12Fr, 5-10mL	F01A081205
		12Fr, 10mL	F01A081207
		12Fr, 15mL	F01A081208
		12Fr, 15-30mL	F01A081209
		12Fr, 30mL	F01A081210
		14Fr, 5mL	F01A081404
		14Fr, 5-10mL	F01A081405
		14Fr, 10mL	F01A081407
		14Fr, 15mL	F01A081408
		14Fr, 15-30mL	F01A081409
		14Fr, 30mL	F01A081410
		16Fr, 5mL	F01A081604
		16Fr, 5-10mL	F01A081605
		16Fr, 10mL	F01A081607
		16Fr, 15mL	F01A081608
		16Fr, 30mL	F01A081610
		16Fr, 30-50mL	F01A081612
		18Fr, 5mL	F01A081804
		18Fr, 5-10mL	F01A081805



Basic UDI-DI	Type	Size	REF
69449327FF01A00DX	2-way, Tiemann	18Fr, 10mL	F01A081807
		18Fr, 15mL	F01A081808
		18Fr, 30mL	F01A081810
		18Fr, 30-50mL	F01A081812
		20Fr, 5mL	F01A082004
		20Fr, 5-10mL	F01A082005
		20Fr, 10mL	F01A082007
		20Fr, 15mL	F01A082008
		20Fr, 30mL	F01A082010
		20Fr, 30-50mL	F01A082012
		22Fr, 5mL	F01A082204
		22Fr, 5-10mL	F01A082205
		22Fr, 10mL	F01A082207
		22Fr, 15mL	F01A082208
		22Fr, 30mL	F01A082210
		22Fr, 30-50mL	F01A082212
		24Fr, 5-10mL	F01A082405
		24Fr, 10mL	F01A082407
		24Fr, 15mL	F01A082408
		24Fr, 30mL	F01A082410
		24Fr, 30-50mL	F01A082412
69449327FF01A04E7	3-way	16Fr, 5-10mL	F01A101605
		16Fr, 10mL	F01A101607
		16Fr, 5-15mL	F01A101606
		16Fr, 15mL	F01A101608
		16Fr, 30mL	F01A101610
		16Fr, 30-50mL	F01A101612
		18Fr, 5-10mL	F01A101805
		18Fr, 10mL	F01A101807
		18Fr, 5-15mL	F01A101806
		18Fr, 15mL	F01A101808
		18Fr, 30mL	F01A101810
		18Fr, 30-50mL	F01A101812
		20Fr, 5-10mL	F01A102005
		20Fr, 10mL	F01A102007
		20Fr, 5-15mL	F01A102006
		20Fr, 15mL	F01A102008
		20Fr, 30mL	F01A102010
		20Fr, 30-50mL	F01A102012
		22Fr, 5-10mL	F01A102205
		22Fr, 10mL	F01A102207
		22Fr, 5-15mL	F01A102206
		22Fr, 15mL	F01A102208
		22Fr, 30mL	F01A102210
		22Fr, 30-50mL	F01A102212
		24Fr, 5-10mL	F01A102405
		24Fr, 10mL	F01A102407
		24Fr, 5-15mL	F01A102406
		24Fr, 15mL	F01A102408





Basic UDI-DI	Type	Size	REF
69449327FF01A04E7	3-way	24Fr, 30mL	F01A102410
		24Fr, 30-50mL	F01A102412
		26Fr, 5-10mL	F01A102605
		26Fr, 10mL	F01A102607
		26Fr, 5-15mL	F01A102606
		26Fr, 15mL	F01A102608
		26Fr, 30mL	F01A102610
		26Fr, 30-50mL	F01A102612

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 801167 R000

Manufacturer: Well Lead Medical Co., Ltd.

Address:

C-4 Jinhu Industrial Estate
Hualong Panyu
Guangzhou
Guangdong
511434
China

Single Registration Number: CN-MF-000006728

EU Authorised Representative: Shanghai International Holding Corp. GmbH (Europe)

Address:

Eiffestrasse 80
Hamburg
20537
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-12-14**

Current Issue Date: **2023-12-14**

Starting Validity Date: **2023-12-14**

Expiry Date: **2028-12-13**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 801167 R000

Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Latex Foley Catheter	Latex Foley is inserted into the bladder through urethra and are indicated for routine urine drainage or for routine post-operative drainage and irrigation bladder.
All Silicone Foley Catheter	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.

First Issue Date: **2023-12-14**

Current Issue Date: **2023-12-14**

Starting Validity Date: **2023-12-14**

Expiry Date: **2028-12-13**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.



By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 801167 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	30056657	Issued



First Issue Date: **2023-12-14**

Current Issue Date: **2023-12-14**

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Page 3 of 3

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