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Document Nr.: WL-MDR-DOC-004-01/A

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

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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**

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

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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	

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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	

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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	

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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	

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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	

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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	

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