Declaration of Conformity

Manufacturer:	**Well Lead Medical Co., Ltd.** 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)** Eiffestrasse 80, 20537 Hamburg, GERMANY
Product Name:	All Silicone Foley Catheter
Intended Purpose:	All Silicone Foley Catheter is intended to be used by trained person or healthcare professionals for transurethral or suprapubic drainage. The 3-way model can be used for irrigation of the 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 8**

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 13485:2016 + A11:2021 / EN ISO 20696:2018/ EN ISO 20697:2018/ ISO7886.1-2017/ EN ISO 14971:2019/ CEN ISO/TR 24971:2020/ 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 10993-12:2012/ 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/ SCHEER guidelines/ ISTA 2A/ ASTM F1980-21/ MEDDEV 2.7.1 rev.4/ MDCG 2020-5/ MDCG 2020-6/ EN ISO 11135:2014+A1:2019

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:	Initial issued: 2023-12-14 Amended -Update to the intended purpose for All Silicone Foley Catheter: 2025-03-07

Signature: 

Name: Chen Yun Gui

Position: Management Representative & PRRC

Place, Date of Issue: Guangzhou, 2025-03-07

Table1 Catalogue Number

Model	Type	Size	Balloon Volume	Wellead REF	Medline REF	DESCRIPTION	Basic UDI-DI
All Silicone Foley Catheter	2-way, Pediatric	6Fr	1.5ml	F01B040601	641006A	Silicone Foley Catheter, 2 Way Pediatric 6FR 1.5ml	69449327FF01B01E6
		8Fr	3-5ml	F01B040803	641008A	Silicone Foley Catheter, 2 Way Pediatric 8FR 3-5ml	
		10Fr	3-5ml	F01B041003	641010A	Silicone Foley Catheter, 2 Way Pediatric 10FR 3-5ml	
	2-way, Standard	12Fr	5-15ml	F01B011206	642112A	Silicone Foley Catheter, 2 Way Nelaton 12FR 5-15ml	69449327FF01B00E4
		14Fr	5-15mL	F01B011406	642114A	Silicone Foley Catheter, 2 Way Nelaton 14FR 5-15ml	
		16Fr	5-15mL	F01B011606	642116A	Silicone Foley Catheter, 2 Way Nelaton 16FR 5-15ml	
		18Fr	5-15mL	F01B011806	642118A	Silicone Foley Catheter, 2 Way Nelaton 18FR 5-15ml	
		20Fr	5-15mL	F01B012006	642120A	Silicone Foley Catheter, 2 Way Nelaton 20FR 5-15ml	
		22Fr	5-15mL	F01B012206	642122A	Silicone Foley Catheter, 2 Way Nelaton 22FR 5-15ml	
		24Fr	5-15mL	F01B012406	642124A	Silicone Foley Catheter, 2 Way Nelaton 24FR 5-15ml	
		16Fr	30mL	F01B031610	643016A	Silicone Foley Catheter, 2 Way Nelaton 16FR 30ml	
		18Fr	30mL	F01B031810	643018A	Silicone Foley Catheter, 2 Way Nelaton 18FR 30ml	
		20Fr	30mL	F01B032010	643020A	Silicone Foley Catheter, 2 Way Nelaton 20FR 30ml	
		22Fr	30mL	F01B032210	643022A	Silicone Foley Catheter, 2 Way Nelaton 22FR 30ml	
		24Fr	30mL	F01B032410	643024A	Silicone Foley Catheter, 2 Way Nelaton 24FR 30ml	
		12Fr	10ml	F01B171207	642012A-P	Silicone Foley Catheter with Prefilled Syringe 12FR 10ml	
		14Fr	10ml	F01B171407	642014A-P	Silicone Foley Catheter with Prefilled Syringe 14FR 10ml	
		16Fr	10ml	F01B171607	642016A-P	Silicone Foley Catheter with Prefilled Syringe 16FR 10ml	

Model	Type	Size	Balloon Volume	Wellead REF	Medline REF	DESCRIPTION	Basic UDI-DI
All Silicone Foley Catheter	2-way, Standard	18Fr	10ml	F01B171807	642018A-P	Silicone Foley Catheter with Prefilled Syringe 18FR 10ml	69449327FF01B00E4
		20Fr	10ml	F01B172007	642020A-P	Silicone Foley Catheter with Prefilled Syringe 20FR 10ml	
		22Fr	10ml	F01B172207	642022A-P	Silicone Foley Catheter with Prefilled Syringe 22FR 10ml	
		24Fr	10ml	F01B172407	642024A-P	Silicone Foley Catheter with Prefilled Syringe 24FR 10ml	
	2-way, Tiemann	12Fr	10ml	F01B051205	653012A	Silicone Foley Catheter, 2 Way Tiemann 12FR 10ml	
		14Fr	10ml	F01B051405	653014A	Silicone Foley Catheter, 2 Way Tiemann 14FR 10ml	
		16Fr	10ml	F01B051605	653016A	Silicone Foley Catheter, 2 Way Tiemann 16FR 10ml	
		18Fr	10ml	F01B051805	653018A	Silicone Foley Catheter, 2 Way Tiemann 18FR 10ml	
		20Fr	10ml	F01B052005	653020A	Silicone Foley Catheter, 2 Way Tiemann 20FR 10ml	
	2-way, Open tip	8Fr	3ml	U07B050802	645008A	Silicone Foley Catheter, 2 Way Open Tip 8FR 3ml	
		10Fr	3-5ml	U07B051003	645010A	Silicone Foley Catheter, 2 Way Open Tip 10FR 3-5ml	
		12Fr	5-10ml	U07B061205	645012A	Silicone Foley Catheter, 2 Way Open Tip 12FR 5-10ml	
		14Fr	5-10ml	U07B061405	645014A	Silicone Foley Catheter, 2 Way Open Tip 14FR 5-10ml	
		16Fr	5-10ml	U07B061605	645016A	Silicone Foley Catheter, 2 Way Open Tip 16FR 5-10ml	
		18Fr	5-10ml	U07B061805	645018A	Silicone Foley Catheter, 2 Way Open Tip 18FR 5-10ml	
		20Fr	5-10ml	U07B062005	645020A	Silicone Foley Catheter, 2 Way Open Tip 20FR 5-10ml	
		22Fr	5-10ml	U07B062205	645022A	Silicone Foley Catheter, 2 Way Open Tip 22FR 5-10ml	
		24Fr	5-10ml	U07B062405	645024A	Silicone Foley Catheter, 2 Way Open Tip 24FR 5-10ml	
		26Fr	5-10ml	U07B062605	645026A	Silicone Foley Catheter, 2 Way Open Tip 26FR 5-10ml	

Model	Type	Size	Balloon Volume	Wellead REF	Medline REF	DESCRIPTION	Basic UDI-DI
All Silicone Foley Catheter	3-way, Standard	16Fr	30ml	F01B061610	644016A	Silicone Foley Catheter, 3 Way Nelaton 16FR 30ml	69449327FF01B09EN
		18Fr	30ml	F01B061810	644018A	Silicone Foley Catheter, 3 Way Nelaton 18FR 30ml	
		20Fr	30ml	F01B062010	644020A	Silicone Foley Catheter, 3 Way Nelaton 20FR 30ml	
		22Fr	30ml	F01B062210	644022A	Silicone Foley Catheter, 3 Way Nelaton 22FR 30ml	
		24Fr	30ml	F01B062410	644024A	Silicone Foley Catheter, 3 Way Nelaton 24FR 30ml	