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:	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+A11:2021, CEN ISO/TR 24971:2020, ISO 80369-7: 2021, ISO 2004:2024, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN ISO 14644-3:2019, EN ISO 14644-4:2022, EN ISO 14644-5:2004, EN ISO 14644-7:2004, EN ISO 14644-8:2022, EN ISO 14644-9:2022, EN ISO 14644-10:2022, EN ISO 14644-13:2017, EN ISO 14644-14:2016, EN ISO 14644-16:2019, EN ISO 14644-17:2021, EN ISO11135:2014+A1:2019, EN ISO 11138-1:2017, EN ISO 11138-2:2017, EN ISO 11607-1:2020+A1:2023, EN ISO 11607-2:2020+A1:2023, EN ISO 11737-1:2018+A1:2021, 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+A1:2022, EN ISO 10993-10:2023, EN ISO 10993-11:2018, EN ISO 10993-12:2021, EN ISO 10993-17:2023, EN ISO 10993-18:2020+A1:2023, 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, EN ISO 7886-1:2018, ASTM F2052-21, ASTM F2213-17, ASTM F2182-19e2, ASTM F2119-24

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:	Please refer to Table 1

Signature:

Name: Chen Yungui

Position: **Management Representative & PRRC**

Place, Date of Issue: **Guangzhou, 2025-1-17**

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

Table1 Catalogue Number

Basic UDI-DI	Type	Size	Wellead REF (Hard valve)	Medline REF (Hard valve)	DESCRIPTION	Start of MDR CE Marking (Hard valve)	Wellead REF (Soft valve)	Medline REF (Soft valve)	DESCRIPTION	Start of MDR CE Marking (Soft valve)
6944 9327 FF01 A01D Z	2-way, Pediatric	6Fr, 3mL	F01A060602	661006A	Latex Foley Catheter, 2 Way Nelaton 6FR 3ml, plastic valve	2023/12/14	/			
		8Fr, 3-5mL	F01A060803	661008A	Latex Foley Catheter, 2 Way Nelaton 8FR 3-5ml, plastic valve					
		10Fr, 3mL	F01A061002	661010A	Latex Foley Catheter, 2 Way Nelaton 10FR 3-5ml, plastic valve					
6944 9327 FF01 A00D X	2-way, Standard	12Fr, 5-10mL	F01A021205	662012A	Latex Foley Catheter, 2 Way Nelaton 12FR 5-10ml, plastic valve		F01A011205	662212A	Latex Foley Catheter, 2 Way Nelaton 12FR 5-10ml, rubber valve	2025/1/16

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Basic UDI-DI	Type	Size	Wellead REF (Hard valve)	Medline REF (Hard valve)	DESCRIPTION	Start of MDR CE Marking (Hard valve)	Wellead REF (Soft valve)	Medline REF (Soft valve)	DESCRIPTION	Start of MDR CE Marking (Soft valve)
6944 9327 FF01 A00D X	2-way, Standard	12Fr, 30mL	F01A021210	663012A	Latex Foley Catheter, 2 Way Nelaton 12FR 30ml, plastic valve	2023/12/14	/			
		14Fr, 5-10mL	F01A021405	662014A	Latex Foley Catheter, 2 Way Nelaton 14FR 5-10ml, plastic valve		F01A011405	662214A	Latex Foley Catheter, 2 Way Nelaton 14FR 5-10ml, rubber valve	2025/1/16
		14Fr, 30mL	F01A021410	663014A	Latex Foley Catheter, 2 Way Nelaton 14FR 30ml, plastic valve		/			
		16Fr, 5-10mL	F01A021605	662016A	Latex Foley Catheter, 2 Way Nelaton 16FR 5-10ml, plastic valve		F01A011605	662216A	Latex Foley Catheter, 2 Way Nelaton 16FR 5-10ml, rubber valve	2025/1/16
		16Fr, 30mL	F01A021610	663016A	Latex Foley Catheter, 2 Way Nelaton 16FR 30ml, plastic valve		/			

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Basic UDI-DI	Type	Size	Wellead REF (Hard valve)	Medline REF (Hard valve)	DESCRIPTION	Start of MDR CE Marking (Hard valve)	Wellead REF (Soft valve)	Medline REF (Soft valve)	DESCRIPTION	Start of MDR CE Marking (Soft valve)
6944 9327 FF01 A00D X	2-way, Standard	18Fr, 5-10mL	F01A021805	662018A	Latex Foley Catheter, 2 Way Nelaton 18FR 5-10ml, plastic valve	2023/12/14	F01A011805	662218A	Latex Foley Catheter, 2 Way Nelaton 18FR 5-10ml, rubber valve	2025/1/16
		18Fr, 30mL	F01A021810	663018A	Latex Foley Catheter, 2 Way Nelaton 18FR 30ml, plastic valve		/			
		20Fr, 5-10mL	F01A022005	662020A	Latex Foley Catheter, 2 Way Nelaton 20FR 5-10ml, plastic valve		F01A012005	662220A	Latex Foley Catheter, 2 Way Nelaton 20FR 5-10ml, rubber valve	2025/1/16
		20Fr, 30mL	F01A022010	663020A	Latex Foley Catheter, 2 Way Nelaton 20FR 30ml, plastic valve		/			

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Basic UDI-DI	Type	Size	Wellead REF (Hard valve)	Medline REF (Hard valve)	DESCRIPTION	Start of MDR CE Marking (Hard valve)	Wellead REF (Soft valve)	Medline REF (Soft valve)	DESCRIPTION	Start of MDR CE Marking (Soft valve)
6944 9327 FF01 A00D X	2-way, Standard	22Fr, 5-10mL	F01A022205	662022A	Latex Foley Catheter, 2 Way Nelaton 22FR 5-10ml, plastic valve	2023/12/14	F01A012205	662222A	Latex Foley Catheter, 2 Way Nelaton 22FR 5-10ml, rubber valve	2025/1/16
		22Fr, 30mL	F01A022210	663022A	Latex Foley Catheter, 2 Way Nelaton 22FR 30ml, plastic valve		/			
		24Fr, 5-10mL	F01A022405	662024A	Latex Foley Catheter, 2 Way Nelaton 24FR 5-10ml, plastic valve		F01A012405	662224A	Latex Foley Catheter, 2 Way Nelaton 24FR 5-10ml, rubber valve	2025/1/16
		24Fr, 30mL	F01A022410	663024A	Latex Foley Catheter, 2 Way Nelaton 24FR 30ml, plastic valve		/			

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Basic UDI-DI	Type	Size	Wellead REF (Hard valve)	Medline REF (Hard valve)	DESCRIPTION	Start of MDR CE Marking (Hard valve)	Wellead REF (Soft valve)	Medline REF (Soft valve)	DESCRIPTION	Start of MDR CE Marking (Soft valve)
69449327FF01A00DX	2-way, Standard	26Fr, 5-10mL	F01A022605	662026A	Latex Foley Catheter, 2 Way Nelaton 26FR 5-10ml, plastic valve	2023/12/14	F01A012605	662226A	Latex Foley Catheter, 2 Way Nelaton 26FR 5-10ml, rubber valve	/
		26Fr, 30mL	F01A022610	663026A	Latex Foley Catheter, 2 Way Nelaton 26FR 30ml, plastic valve		/			
	2-way,Tiemann	12Fr, 5-10mL	F01A081205	665012A	Latex Foley Catheter, 2 Way Tiemann 12FR 5-10ml, plastic valve					
		12Fr, 30mL	F01A081210	666012A	Latex Foley Catheter, 2 Way Tiemann 12FR 30ml, plastic valve					
		14Fr, 5-10mL	F01A081405	665014A	Latex Foley Catheter, 2 Way Tiemann 14FR 5-10ml, plastic valve					

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Basic UDI-DI	Type	Size	Wellead REF (Hard valve)	Medline REF (Hard valve)	DESCRIPTION	Start of MDR CE Marking (Hard valve)	Wellead REF (Soft valve)	Medline REF (Soft valve)	DESCRIPTION	Start of MDR CE Marking (Soft valve)
6944 9327 FF01 A00D X	2-way,Tiemann	14Fr, 30mL	F01A081410	666014A	Latex Foley Catheter, 2 Way Tiemann 14FR 30ml, plastic valve	2023/12/14	/			
		16Fr, 5-10mL	F01A081605	665016A	Latex Foley Catheter, 2 Way Tiemann 16FR 5-10ml, plastic valve					
		16Fr, 30mL	F01A081610	666016A	Latex Foley Catheter, 2 Way Tiemann 16FR 30ml, plastic valve					
		18Fr, 5-10mL	F01A081805	665018A	Latex Foley Catheter, 2 Way Tiemann 18FR 5-10ml, plastic valve					
		18Fr, 30mL	F01A081810	666018A	Latex Foley Catheter, 2 Way Tiemann 18FR 30ml, plastic valve					
		20Fr, 5-10mL	F01A082005	665020A	Latex Foley Catheter, 2 Way Tiemann 20FR 5-10ml, plastic valve					

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Basic UDI-DI	Type	Size	Wellead REF (Hard valve)	Medline REF (Hard valve)	DESCRIPTION	Start of MDR CE Marking (Hard valve)	Wellead REF (Soft valve)	Medline REF (Soft valve)	DESCRIPTION	Start of MDR CE Marking (Soft valve)
6944 9327 FF01 A00D X	2-way,Tiemann	20Fr, 30mL	F01A082010	666020A	Latex Foley Catheter, 2 Way Tiemann 20FR 30ml, plastic valve	2023/12/14	/			
6944 9327 FF01 A04E 7	3-way	16Fr, 30mL	F01A101610	668016A	Latex Foley Catheter, 3 Way Nelaton 16FR 30ml, plastic valve					
		18Fr, 30mL	F01A101810	668018A	Latex Foley Catheter, 3 Way Nelaton 18FR 30ml, plastic valve					
		20Fr, 30mL	F01A102010	668020A	Latex Foley Catheter, 3 Way Nelaton 20FR 30ml, plastic valve					
		22Fr, 30mL	F01A102210	668022A	Latex Foley Catheter, 3 Way Nelaton 22FR 30ml, plastic valve					
		24Fr, 30-50mL	F01A102412	668024A	Latex Foley Catheter, 3 Way Nelaton 24FR 30ml, plastic valve					

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6944 9327 FF01 A04E 7	3-way	26Fr, 30mL	F01A102610	668026A	Latex Foley Catheter, 3 Way Nelaton 26FR 30ml, plastic valve	2023/12/14	/			

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