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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

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
Tel: +86 20 84758878
Web: https://www.wellead.com/

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Table1 Catalogue Number

Model	Type	Basic UDI-DI	Size	Wellead REF	Asid Bonz REF	DESCRIPTION
All Silicone Foley Catheter	2-way, Pediatric	69449327FF01B01E6	6Fr	F01B040601	641006	Silicone Foley Catheter, 2 Way Nelaton 6FR 1.5ml
			8Fr	F01B040803	641008	Silicone Foley Catheter, 2 Way Nelaton 8FR 3-5ml
			10Fr	F01B041003	641010	Silicone Foley Catheter, 2 Way Nelaton 10FR 3-5ml
	2-way, Standard	69449327FF01B01E4	12Fr	F01B011206	642112	Silicone Foley Catheter, 2 Way Nelaton 12FR 5-15ml
			14Fr	F01B011406	642114	Silicone Foley Catheter, 2 Way Nelaton 14FR 5-15ml
			16Fr	F01B011606	642116	Silicone Foley Catheter, 2 Way Nelaton 16FR 5-15ml
			18Fr	F01B011806	642118	Silicone Foley Catheter, 2 Way Nelaton 18FR 5-15ml
			20Fr	F01B012006	642120	Silicone Foley Catheter, 2 Way Nelaton 20FR 5-15ml
			22Fr	F01B012206	642122	Silicone Foley Catheter, 2 Way Nelaton 22FR 5-15ml
			24Fr	F01B012406	642124	Silicone Foley Catheter, 2 Way Nelaton 24FR 5-15ml
			16Fr	F01B011610	643016	Silicone Foley Catheter, 2 Way Nelaton 16FR 30ml
			18Fr	F01B011810	643018	Silicone Foley Catheter, 2 Way Nelaton 18FR 30ml
			20Fr	F01B012010	643020	Silicone Foley Catheter, 2 Way Nelaton 20FR 30ml
			22Fr	F01B012210	643022	Silicone Foley Catheter, 2 Way Nelaton 22FR 30ml
			24Fr	F01B012410	643024	Silicone Foley Catheter, 2 Way Nelaton 24FR 30ml
			16Fr	F01B061610	644016	Silicone Foley Catheter, 3 Way Nelaton 16FR 30ml
			18Fr	F01B061810	644018	Silicone Foley Catheter, 3 Way Nelaton 18FR 30ml
			20Fr	F01B062010	644020	Silicone Foley Catheter, 3 Way Nelaton 20FR 30ml
			22Fr	F01B062210	644022	Silicone Foley Catheter, 3 Way Nelaton 22FR 30ml
			24Fr	F01B062410	644024	Silicone Foley Catheter, 3 Way Nelaton 24FR 30ml
	2-way, Tiemann	69449327FF01B05EE	12Fr	F01B051207	653012	Silicone Foley Catheter, 2 Way Tiemann 12FR 10ml
			14Fr	F01B051405	653014	Silicone Foley Catheter, 2 Way Tiemann 14FR 10ml
			16Fr	F01B051607	653016	Silicone Foley Catheter, 2 Way Tiemann 16FR 10ml
			18Fr	F01B051807	653018	Silicone Foley Catheter, 2 Way Tiemann 18FR 10ml
			20Fr	F01B052007	653020	Silicone Foley Catheter, 2 Way Tiemann 20FR 10ml
	2-way, Standard	69449327FF01B01E4	12Fr	F01B171207	642012-P	Silicone Foley Catheter with Prefilled Syringe 12FR 10ml
			14Fr	F01B171407	642014-P	Silicone Foley Catheter with Prefilled Syringe 14FR 10ml

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Model	Type	Basic UDI-DI	Size	Wellead REF	Asid Bonz REF	DESCRIPTION
			16Fr	F01B171607	642016-P	Silicone Foley Catheter with Prefilled Syringe 16FR 10ml
			18Fr	F01B171807	642018-P	Silicone Foley Catheter with Prefilled Syringe 18FR 10ml
			20Fr	F01B172007	642020-P	Silicone Foley Catheter with Prefilled Syringe 20FR 10ml
			22Fr	F01B172207	642022-P	Silicone Foley Catheter with Prefilled Syringe 22FR 10ml
			24Fr	F01B172407	642024-P	Silicone Foley Catheter with Prefilled Syringe 24FR 10ml

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