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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/

Table1 Catalogue Number

Model	Type	Basic UDI-DI	Size	Balloon Volume	Wellead Ref. No.	B Braun Ref. No.	Description
All Silicone Foley Catheter	2-way, Pediatric	69449327F F01B01E6	8Fr	3ml	F01B040802	4563308	Urimed Cath Foley Nelaton CH08
			10Fr	3ml	F01B041002	4563310	Urimed Cath Foley Nelaton CH10
	2-way, Standard	69449327F F01B01E4	12Fr	10ml	F01B011207	4563312	Urimed Cath Foley Nelaton CH12
			14Fr	10mL	F01B011407	4563314	Urimed Cath Foley Nelaton CH14
			16Fr	10mL	F01B011607	4563316	Urimed Cath Foley Nelaton CH16
			18Fr	10mL	F01B011807	4563318	Urimed Cath Foley Nelaton CH18
			20Fr	10mL	F01B012007	4563320	Urimed Cath Foley Nelaton CH20
			22Fr	10mL	F01B012207	4563322	Urimed Cath Foley Nelaton CH22
			24Fr	10mL	F01B012407	4563324	Urimed Cath Foley Nelaton CH24
	2-way, Tiemann	69449327F F01B05EE	12Fr	10ml	F01B051207	4563412	Urimed Cath Foley Tiemann CH12
			14Fr	10ml	F01B051405	4563414	Urimed Cath Foley Tiemann CH14
			16Fr	10ml	F01B051607	4563416	Urimed Cath Foley Tiemann CH16
			18Fr	10ml	F01B051807	4563418	Urimed Cath Foley Tiemann CH18
			20Fr	10ml	F01B052007	4563420	Urimed Cath Foley Tiemann CH20

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