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	REF (Hard valve)	REF (Hard valve)-GHC	Start of MDR CE Marking
69449327FF01A00DX	2-way,Standard	12Fr, 10mL	F01A021207	01/01/13/12/10/GHC	2023/12/14
		14Fr, 10mL	F01A021407	01/01/13/14/10/GHC	
		16Fr, 30mL	F01A021610	01/01/13/16/30/GHC	
		18Fr, 30mL	F01A021810	01/01/13/18/30/GHC	
		20Fr, 30mL	F01A022010	01/01/13/20/30/GHC	
		22Fr, 30mL	F01A022210	01/01/13/22/30/GHC	
		24Fr, 30mL	F01A022410	01/01/13/24/30/GHC	

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