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Document Nr.: WL-MDR-DOC-001-01/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:	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, CEN ISO/TR 24971:2020, ISO 80369-7: 2021, ISO 2004:2017, 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, ENISO11135:2014+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-

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1:2015+AMD1:2020, ISTA 2A, ASTM F1980-21, MDCG 2020-5, MDCG 2020-6, 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 Yungui

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
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Table1 Catalogue Number

Basic UDI-DI	Type	Wellead REF	Asid Bonz REF	DESCRIPTION
69449327FF01A01DZ	2-way, Pediatric	F01A060602	661006	Latex Foley Catheter, 2 Way Nelaton 6FR 3ml, plastic valve
		F01A060803	661008	Latex Foley Catheter, 2 Way Nelaton 8FR 3-5ml, plastic valve
		F01A061003	661010	Latex Foley Catheter, 2 Way Nelaton 10FR 3-5ml, plastic valve
69449327FF01A00DX	2-way, standard	F01A021205	662012	Latex Foley Catheter, 2 Way Nelaton 12FR 5-10ml, plastic valve
		F01A021405	662014	Latex Foley Catheter, 2 Way Nelaton 14FR 5-10ml, plastic valve
		F01A021605	662016	Latex Foley Catheter, 2 Way Nelaton 16FR 5-10ml, plastic valve
		F01A021805	662018	Latex Foley Catheter, 2 Way Nelaton 18FR 5-10ml, plastic valve
		F01A022005	662020	Latex Foley Catheter, 2 Way Nelaton 20FR 5-10ml, plastic valve
		F01A022205	662022	Latex Foley Catheter, 2 Way Nelaton 22FR 5-10ml, plastic valve
		F01A022405	662024	Latex Foley Catheter, 2 Way Nelaton 24FR 5-10ml, plastic valve
		F01A022605	662026	Latex Foley Catheter, 2 Way Nelaton 26FR 5-10ml, plastic valve
		F01A021210	663012	Latex Foley Catheter, 2 Way Nelaton 12FR 30ml, plastic valve
		F01A021410	663014	Latex Foley Catheter, 2 Way Nelaton 14FR 30ml, plastic valve
		F01A021610	663016	Latex Foley Catheter, 2 Way Nelaton 16FR 30ml, plastic valve
		F01A021810	663018	Latex Foley Catheter, 2 Way Nelaton 18FR 30ml, plastic valve
		F01A022010	663020	Latex Foley Catheter, 2 Way Nelaton 20FR 30ml, plastic valve
		F01A022210	663022	Latex Foley Catheter, 2 Way Nelaton 22FR 30ml, plastic valve
		F01A022410	663024	Latex Foley Catheter, 2 Way Nelaton 24FR 30ml, plastic valve
		F01A022610	663026	Latex Foley Catheter, 2 Way Nelaton 26FR 30ml, plastic valve
69449327FF01A00DX	2-way, Tiemann	F01A081205	665012	Latex Foley Catheter, 2 Way Tiemann 12FR 5-10ml, plastic valve
		F01A081405	665014	Latex Foley Catheter, 2 Way Tiemann 14FR 5-10ml, plastic valve
		F01A081605	665016	Latex Foley Catheter, 2 Way Tiemann 16FR 5-10ml, plastic valve
		F01A081805	665018	Latex Foley Catheter, 2 Way Tiemann 18FR 5-10ml, plastic valve
		F01A082005	665020	Latex Foley Catheter, 2 Way Tiemann 20FR 5-10ml, plastic valve
		F01A081210	666012	Latex Foley Catheter, 2 Way Tiemann 12FR 30ml, plastic valve
		F01A081410	666014	Latex Foley Catheter, 2 Way Tiemann 14FR 30ml, plastic valve
		F01A081610	666016	Latex Foley Catheter, 2 Way Tiemann 16FR 30ml, plastic valve

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		F01A081810	666018	Latex Foley Catheter, 2 Way Tiemann 18FR 30ml, plastic valve
		F01A082010	666020	Latex Foley Catheter, 2 Way Tiemann 20FR 30ml, plastic valve
69449327FF01A04E7	3-way	F01A101610	668016	Latex Foley Catheter, 3 Way Nelaton 16FR 30ml, plastic valve
		F01A101810	668018	Latex Foley Catheter, 3 Way Nelaton 18FR 30ml, plastic valve
		F01A102010	668020	Latex Foley Catheter, 3 Way Nelaton 20FR 30ml, plastic valve
		F01A102210	668022	Latex Foley Catheter, 3 Way Nelaton 22FR 30ml, plastic valve
		F01A102410	668024	Latex Foley Catheter, 3 Way Nelaton 24FR 30ml, plastic valve
		F01A102610	668026	Latex Foley Catheter, 3 Way Nelaton 26FR 30ml, plastic valve

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