wellead 维力

Document Nr.: WL-MDR-DOC-22-01-01/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)** Eiffestrasse 80, 20537 Hamburg, GERMANY
SRN:	DE-AR-000000001
Product Name:	All Silicone Foley Catheter with Temperature Sensor
Intended Purpose:	All Silicone Foley Catheter with Temperature Sensor is passed through the urethra during urinary catheterization and into the bladder to drain urine, the temperature sensor can be used to monitor the bladder temperature during drainage to assist clinical diagnosis. It is intended for temperature monitoring in patients that are catheterized because of fluid management problems, evaluation of urinary output, urine clearance following surgery or trauma involving pelvic organs, or obstruction and paralysis. MRI compatible.
Type/ Size/ Catalogue Number:	Please refer to Table 1
UMDNS Code:	10720
GMDN Code:	46629
EMDN Code:	U0103
Basic UDI-DI:	Please refer to Table 1

WELL LEAD MEDICAL CO. LTD. 广州维力医疗器械股份有限公司

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 above mentioned products 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 13485:2016 + A11:2021 / EN ISO 20696:2018/ EN ISO 14971:2019/ CEN ISO/TR 24971:2020/ 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 10993-12:2012/ 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/ SCHEER guidelines/ ISTA 2A/ ASTM F1980-16/ MEDDEV 2.7.1 rev.4/ MDCG 2020-5/ MDCG 2020-6/ MDCG 2020-7/ EN ISO 11135:2014+A1:2019 EN 17141:2020/ EN 556-1:2001/AC:2006/ EN 556-2:2015/
EN 15986:2011/ 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 14644-15:2017/ EN ISO 14644-16:2019 / EN ISO 14644-17:2021/ 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+A1:2021/ EN ISO 11737-2:2020/ ASTM F1929-15/ EN 868-5:2018/ ASTM F1886-16/ ASTM F88-21

Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany
Identification number:	CE0123
(EC) Certificate(s):	G10 038814 0095 Rev. 01
Expire date of the Certificate:	2028-12-05
Start of MDR CE Marking:	Please refer to Table 1

WELLEAD MEDICAL CO., LTD. 广州维力医疗器械股份有限公司

Signature:

Name: Chen Yun Gui

Position: Management Representative & PRRC

Place, Date of Issue: Guangzhou, 2026-08-10

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

Table1

Type	Basic UDI-DI	Size	Balloon Volumn	Wellead Catalogue Number	Unoquip Catalogue Number	Start of MDR CE Marking
2-way, Pediatric	69449327FF01C00E9	6Fr	1.5mL	F01C010601	42220601	2026-07-07
		8Fr	3mL	F01C010802	42220803	2023-12-06
		10Fr	5mL	F01C011004	42221005	2023-12-06
2-way, standard	69449327FF01C01EB	12Fr	10mL	F01C011207	42221210	2023-12-06
		14Fr	10mL	F01C011407	42221410	2023-12-06
		16Fr	10mL	F01C011607	42221610	2023-12-06
		18Fr	10mL	F01C011807	42221810	2023-12-06
		20Fr	10mL	F01C012007	42222010	2023-12-06
		22Fr	10mL	F01C012207	42222210	2023-12-06
		24Fr	10mL	F01C012407	42222410	2023-12-06
2-way, Small Tiemann	69449327FF01C01EB	12Fr	10mL	F01C041207	42231210	2026-07-07
		14Fr	10mL	F01C041407	42231410	2026-07-07
		16Fr	10mL	F01C041607	42231610	2026-07-07
		18Fr	10mL	F01C041807	42231810	2026-07-07



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