wellead 维力

Document Nr.: WL-MDR-DOC-022-01-17/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

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 20696:2018/ EN ISO 13485:2016 + A11:2021 / 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 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 0388140095 Rev.00
Expire date of the Certificate:	2028/12/5
Start of MDR CE Marking:	2023/12/6

Signature:

Name: Chen Yun Gui

Position: Management Representative & PRRC

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

Place, Date of Issue: Guangzhou, 2023-12-06

Table1

Type	Basic UDI-DI	Size	Balloon volume/ mL	Catalogue Number	Medline REF	DESCRIPTION
2-way, Pediatric	69449327FF01C00E9	8Fr	5	F01C010804	646008A	All Silicone Foley Catheter with Temperature Sensor, 2 Way 8FR 5ml
		10Fr	5	F01C011004	646010A	All Silicone Foley Catheter with Temperature Sensor, 2 Way 10FR 5ml
2-way, standard	69449327FF01C01EB	12Fr	10	F01C011207	646012A	All Silicone Foley Catheter with Temperature Sensor, 2 Way 12FR 10ml
		14Fr	10	F01C011407	646014A	All Silicone Foley Catheter with Temperature Sensor, 2 Way 14FR 10ml
		16Fr	10	F01C011607	646016A	All Silicone Foley Catheter with Temperature Sensor, 2 Way 16FR 10ml
		18Fr	10	F01C011807	646018A	All Silicone Foley Catheter with Temperature Sensor, 2 Way 18FR 10ml
		20Fr	10	F01C012007	646020A	All Silicone Foley Catheter with Temperature Sensor, 2 Way 20FR 30ml
		22Fr	10	F01C012207	646022A	All Silicone Foley Catheter with Temperature Sensor, 2 Way 22FR 30ml
		24Fr	10	F01C012407	646024A	All Silicone Foley Catheter with Temperature Sensor, 2 Way 24FR 30ml

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

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