wellead 维力

Document Nr.: WL-MDR-DOC-019/A

Declaration of Conformity

Manufacturer:	**Well Lead Medical Co., Ltd.** C-4 Jinhu Industrial Estate, Hualong 511434 Panyu, Guangzhou, People Republic of China
SRN:	CN-MF-000006728
European Representative:	**Shanghai International Holding Corp. GmbH (Europe)** Eiffestrasse 80, 20537 Hamburg, GERMANY
Product Name:	Nelaton Catheter
Intended Purpose:	Nelaton catheter is inserted into the bladder through urethra and are indicated for intermittent urine drainage.
Type/ Size/ Catalogue Number:	Please refer to Table 1
UMDNS Code:	10734
GMDN Code:	34930
EMDN Code:	U01010502
Basic UDI-DI:	69449327FF01D00EE

Classification (MDR, Annex Ⅷ): **IIa, 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.

Confidential

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 20417:2021/ EN ISO 10993-1:2020/ EN ISO 10993-5:2009/ EN ISO 10993-7:2008+AC:2009/ EN ISO 10993-10:2013/ EN ISO 10993-12:2012/ 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

Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany
Identification number:	CE0123
(EC) Certificate(s):	G10 038814 0092 Rev. 00
Expire date of the Certificate:	2028/5/15
Start of MDR CE Marking:	2023/5/16

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

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Table1 Catalogue Number

Type	Size	Catalogue Number
Female	6Fr	F01D02061F
	8 Fr	F01D02081F
	10Fr	F01D02101F
	12Fr	F01D02121F
	14 Fr	F01D02141F
	16Fr	F01D02161F
	18Fr	F01D02181F
	20Fr	F01D02201F
	22Fr	F01D02221F
	24Fr	F01D02241F
Standard	6Fr	F01D01061F
	8 Fr	F01D01081F
	10Fr	F01D01101F
	12Fr	F01D01121F
	14 Fr	F01D01141F
	16Fr	F01D01161F
	18Fr	F01D01181F
	20Fr	F01D01201F
	22Fr	F01D01221F
	24Fr	F01D01241F
Tiemann Tip	10Fr	F01D03101F
	12Fr	F01D03121F
	14 Fr	F01D03141F
	16Fr	F01D03161F
	18Fr	F01D03181F
	20Fr	F01D03201F
	22Fr	F01D03221F

Confidential

Place, Date of Issue:

Signature:

Name: Chen Yun Gui

Position: **Management Representative & PRRC**

Place, Date of Issue: **Guangzhou, 2023-5-18**

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

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