wellead 维力

Document Nr.: WL-MDR-DOC-019-01-17/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
SRN:	DE-AR-000000001
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

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

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.

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. 02
Expire date of the Certificate:	2028/5/15
Start of MDR CE Marking:	2023/5/16

Place, Date of Issue:

Signature: _____

Name: Chen Yun Gui

Position: **Management Representative & PRRC**

Place, Date of Issue: **Guangzhou, 2026-06-05**

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

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

Table1 Catalogue Number

Type	Basi UDI-DI	Size	Wellead REF	Medline REF	DESCRIPTION
Tiemann	69449327FF01D00EE	6Fr	F01D030610	670206A	PVC Nelaton Catheter, Tiemann tip, 6Fr
		8Fr	F01D030810	670208A	PVC Nelaton Catheter, Tiemann tip, 8Fr
		10Fr	F01D03101F	670210A	PVC Nelaton Catheter, Tiemann tip, 10Fr
		12Fr	F01D03121F	670212A	PVC Nelaton Catheter, Tiemann tip, 12Fr
		14Fr	F01D03141F	670214A	PVC Nelaton Catheter, Tiemann tip, 14Fr
		16Fr	F01D03161F	670216A	PVC Nelaton Catheter, Tiemann tip, 16Fr
		18Fr	F01D03181F	670218A	PVC Nelaton Catheter, Tiemann tip, 18Fr
		20Fr	F01D03201F	670220A	PVC Nelaton Catheter, Tiemann tip, 20Fr
		22Fr	F01D03221F	670222A	PVC Nelaton Catheter, Tiemann tip, 22Fr
		24Fr	F01D032410	670224A	PVC Nelaton Catheter, Tiemann tip, 24Fr
Standard		6Fr	F01D01061F	680206A	PVC Nelaton Catheter, Standard, 6Fr
		8Fr	F01D01081F	680208A	PVC Nelaton Catheter, Standard, 8Fr
		10Fr	F01D01101F	680210A	PVC Nelaton Catheter, Standard, 10Fr
		12Fr	F01D01121F	680212A	PVC Nelaton Catheter, Standard, 12Fr
		14Fr	F01D01141F	680214A	PVC Nelaton Catheter, Standard, 14Fr
		16Fr	F01D01161F	680216A	PVC Nelaton Catheter, Standard, 16Fr
		18Fr	F01D01181F	680218A	PVC Nelaton Catheter, Standard, 18Fr
		20Fr	F01D01201F	680220A	PVC Nelaton Catheter, Standard, 20Fr
		22Fr	F01D01221F	680222A	PVC Nelaton Catheter, Standard, 22Fr
		24Fr	F01D01241F	680224A	PVC Nelaton Catheter, Standard, 24Fr
Female		6Fr	F01D02061F	680306A	PVC Nelaton Catheter, Tiemann, 6Fr
		8Fr	F01D02081F	680308A	PVC Nelaton Catheter, Tiemann, 8Fr
		10Fr	F01D02101F	680310A	PVC Nelaton Catheter, Tiemann, 10Fr

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Type	Basi UDI-DI	Size	Wellead REF	Medline REF	DESCRIPTION
		12Fr	F01D02121F	680312A	PVC Nelaton Catheter, Tiemann, 12Fr
		14Fr	F01D02141F	680314A	PVC Nelaton Catheter, Tiemann, 14Fr
		16Fr	F01D02161F	680316A	PVC Nelaton Catheter, Tiemann, 16Fr
		18Fr	F01D02181F	680318A	PVC Nelaton Catheter, Tiemann, 18Fr
		20Fr	F01D02201F	680320A	PVC Nelaton Catheter, Tiemann, 20Fr
		22Fr	F01D02221F	680322A	PVC Nelaton Catheter, Tiemann, 22Fr
		24Fr	F01D02241F	680324A	PVC Nelaton Catheter, Tiemann, 24Fr

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