wellead 维力

Document Nr.: WL-DOC-082/C

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:	Male External Catheter
Type:	Type I, Type II, Type III
Size:	25mm, 28mm, 29mm, 30mm, 32mm, 36mm, 41mm
Catalogue No.	Refer to Annex I
UMDNS Code:	10765
EMDN Code:	U070201
CND Code:	U070201
Basic UDI-DI:	69449327FF03A00ED

Classification (MDR, Annex Ⅷ): **I (Non-sterile), Rule 1**

Conformity Assessment Route: **Technical Documentation (Annex Ⅱ and Annex 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 14971: 2019/ EN ISO 15223-1: 2021/ EN ISO 20417:2021/ EN ISO 10993-1:2020/ EN ISO 10993-5:2009/ EN ISO 10993-10:2013/ ASTM F1980-16/ ISTA 2A/ IEC 62366-1:2015+AMD 1:2020/ EN ISO 14644-1:2015/ EN ISO 14644-2:2015/ MEDDEV 2.7.1 rev.4/ MDCG 2020-5/ MDCG 2020-6/ MDCG 2020-7

Signature: _____

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

Name: Chen Yun Gui

Position: **Management Representative**

Place, Date of Issue: **Guangzhou, 2022-02-28**

Heruntergeladen von Gast (IP 216.73.217.10) am 24.11.2026 um 13:25 Uhr · sana.swiss

Annex I Catalogue No.

Model	Size	Cat. No.
Type Ⅰ	25mm	F03A012510/F03A012520
	28mm	F03A012810/ F03A012820
	29mm	F03A012910/ F03A012920
	30mm	F03A013010/ F03A013020
	32mm	F03A013210/ F03A013220
	36mm	F03A013610/ F03A013620
	41mm	F03A014110/ F03A014120
Type Ⅱ	25mm	F03A022510/ F03A022520
	28mm	F03A022810/ F03A022820
	29mm	F03A022910/ F03A022920
	30mm	F03A023010/ F03A023020
	32mm	F03A023210/ F03A023220
	36mm	F03A023610/ F03A023620
	41mm	F03A024110/ F03A024120
Type Ⅲ	25mm	F03A032510/ F03A032520
	28mm	F03A032810/ F03A032820
	29mm	F03A032910/ F03A032920
	30mm	F03A033010/ F03A033020
	32mm	F03A033210/ F03A033220
	36mm	F03A033610/ F03A033620
	41mm	F03A034110/ F03A034120

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广州维力
医疗器械股份有限公司

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

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