wellead 维力

Document Nr.: WL-MDR-DOC-038-01/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:	Spigot
Intended Purpose:	It is used to inserted into the drainage lumen of foley catheter to temperately stop the urine drainage.
Type/ Size/ Catalogue Number:	Please refer to Table 1
EMDN Code:	A070501
Basic UDI-DI:	69449327FF05A01EV

Classification (MDR, Annex Ⅷ): **Is, Rule 1**

Conformity Assessment Route: Quality Management System (Annex IX, Chapter I & III and section 4) + 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 10993-7:2008+AC:2009/ 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/ EN ISO 11135:2014+A1:2019

Notified Body:	BSI Group The Netherlands B.V.
Identification number:	CE 2797
(EC) Certificate(s):	MDR 776669 R00
Expire date of the Certificate:	2027-12-18
Start of MDR CE Marking:	2022-12-19

Signature:

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

Name: Chen Yan Gui

Position: Management Representative & PRRC

Place, Date of Issue: Guangzhou, 2022-12-20

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

Table1

Size	Catalogue Number	ASID BONA REF	DESCRIPTION
Universal	F05A010110	647010-A	Spigot-A sterile

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