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:	Suprapubic Catheter Set
Intended Purpose:	The Suprapubic Catheter set is intended for percutaneous bladder drainage.
Type/ Size/ Catalogue Number:	Please refer to Table 1
UMDNS Code:	10751
GMDN Code:	32021&34924
EMDN Code:	U040101&U040102&U040199
Basic UDI-DI:	Please refer to Table 1

Classification (MDR, Annex Ⅷ): **IIa, Rule 7**

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 1618:1997/ EN 1618:1997/ ISO 80369-7:2016/ISO 9626:2016/ ISO 20697:2018/ ISO 8669-2:1996/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/EN ISO 10993-10:2013/ EN ISO 10993-11:2018/ IEC 62366-1:2015+AMD1:2020/ SCHEER guidelines/ISTA 2A/ ASTM F1980-21/ MEDDEV 2.7.1 rev.4/EN ISO 11135:2014+A1:2019/ MDCG 2020-5/ MDCG 2020-6/ MDCG 2020-7/EN 17141:2020/ EN 556-1:2001/AC:2006/ EN 556-2:2015/ 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 0388140092 Rev.01
Expire date of the Certificate:	2028/5/15
Start of MDR CE Marking:	2023/12/12

Signature:

Name: Chen Yun Gui

Position: Management Representative & PRRC

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

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

Table1

Model	Basic UDI-DI	Size	Wellead REF	Medline REF	DESCRIPTION
Suprapubic Catheter	69449327FU07B00MH	6Fr	U07B050604	645006A	Suprapubic Silicone Foley Catheter, 2 Way Nelaton 6FR 1.5ml
		8Fr	U07B050804	645008A	Suprapubic Silicone Foley Catheter, 2 Way Nelaton 8FR 3ml
		10Fr	U07B051004	645010A	Suprapubic Silicone Foley Catheter, 2 Way Nelaton 10FR 3-5ml
		12Fr	U07B061204	645012A	Suprapubic Silicone Foley Catheter, 2 Way Nelaton 12FR 5-10ml
		14Fr	U07B061404	645014A	Suprapubic Silicone Foley Catheter, 2 Way Nelaton 14FR 5-10ml
		16Fr	U07B061605	645016A	Suprapubic Silicone Foley Catheter, 2 Way Nelaton 16FR 5-10ml
		18Fr	U07B061805	645018A	Suprapubic Silicone Foley Catheter, 2 Way Nelaton 18FR 5-10ml
		20Fr	U07B062005	645020A	Suprapubic Silicone Foley Catheter, 2 Way Nelaton 20FR 5-10ml
		22Fr	U07B062205	645022A	Suprapubic Silicone Foley Catheter, 2 Way Nelaton 22FR 5-10ml

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