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:	Urine Bag
Intended Purpose:	The Urine Bag is used for the collection and temporary storage of urine. It is intended to be used with an indwelling catheter in incontinent patients, cannot urinate normally, or are requiring continuous bladder drainage.
Type/ Size/ Catalogue Number:	Please refer to Table 1
UMDNS Code:	11301
GMDN Code:	58923
EMDN Code:	A06030301
Basic UDI-DI:	Please refer to Table 1

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 8669-2:1997, ISO 13485:2016+A11:2021, EN ISO 14971:2019+A11:2021, CEN ISO/TR 24971:2020, EN ISO 11135:2014+A1:2019, EN ISO 11138-1:2017, EN ISO 11138-2:2017, EN 556-1:2001/AC:2006, EN 556-2:2015, EN ISO 11737-1:2018+A1:2021, EN ISO 11737-2:2020, EN ISO 10993-7:2008+A1:2022, EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 10993-1:2020, EN ISO 10993-5:2009, ISO 10993-10:2021, EN ISO 10993-12:2021, IEC 62366-1:2015+AMD1:2020, IEC/TR 62366-2:2016, ASTM D4332-13, ASTM D4169-14, ASTM D7386-16, EN ISO 4180:2019, ASTM F1929-15, ASTM F88/F88M-09, EN ISO 11607-1:2020, EN ISO 11607-2:2020, ASTM F1980-21, MDCG 2020-5, MDCG 2020-6, MEDDEV 2.7.1 revision 4, MEDDEV 2.12/1 rev.8, MEDDEV 2.12-2 rev 2 (2012), MDCG 2020-7, MDCG 2020-8, MDCG 2018-1 Rev.4, MDCG 2019-1, SCHEER guidelines

Notified Body:	BSI Group The Netherlands B.V.
Identification number:	CE 2797
(EC) Certificate(s):	MDR 776669 R000
Expire date of the Certificate:	2027-12-18
Start of MDR CE Marking:	2023-12-14

Signature:

Name: Chen Yun Gui

Position: Management Representative & PRRC

Place, Date of Issue: Guangzhou,2023.12.14

WELLEAD 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.wellead.com/

Table1 Catalogue Number

Model	Size	Basic UDI-DI	Janmed REF
Drainage Bag (Type A)	1500 ml	69449327FF04A02EQ	600625
			600630
			601150
	2000 ml		601200
			600210
Drainage Bag (Type B)	2000 ml		600090
			600120
	5000 ml		600250
Leg Bag	500 ml	69449327FF04D01F5	631500
	750 ml		631750
			611750
	1000 ml		624130
			624160
			624190

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