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Document Nr.: WL-MDR-DOC-035-01-17/A

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:	Drainage System
Intended Purpose:	The Drainage Systems are intended to use for body fluid drainage for various surgeries.
Type/ Size/ Catalogue Number:	Please refer to Table 1
UMDNS Code:	11304
GMDN Code:	11305
EMDN Code:	A060102
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 ISO 20697: 2018/ EN ISO 13485:2016 + A11:2021 / EN ISO14971: 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/ AAMI TIR 28:2016/ EN 15986:2011/ 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 10993-10:2013/ EN ISO 10993-11:2018/ EN ISO 10993-12:2021/ EN ISO 10993-17:2009/ EN ISO 10993-18:2020/ ISO/TS 21726:2019/ EN ISO 10993-23:2021/ EN 62366-1:2015+AMD1:2020/ IEC/TR 62366-2:2016/ ASTM F1980-21/ ISTA 2A/ ASTM D4332-22/ ASTM D4169-22/ ASTM D7386-16/ EN ISO 4180:2019/ ASTM F1929-15/ ASTM F88/F88M-21/ EN ISO 11607-1:2020/ EN ISO 11607-2:2020/ MEDDEV 2.7.1 rev.4/ MDCG 2020-5/ MDCG 2020-6/ MEDDEV 2.12/1 rev.8/ MEDDEV 2.12-2 rev 2 (2012)/ MDCG 2020-7/ MDCG 2020-8/ SCHEER guidelines/ MDCG 2018-1 Rev.4/ MDCG 2019-1

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Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany
Identification number:	CE0123
(EC) Certificate(s):	G10 038814 0092 Rev.01
Expire date of the Certificate:	2028-05-15
Start of MDR CE Marking:	2024-09-14

Signature:

Name: Chen Yungui

Position: **Management Representative & PRRC**

Place, Date of Issue: **Guangzhou, 2024-09-14**

Table1

Model	Basic-UDI	Size	WELLLEAD Catalogue Number	Medline REF	DESCRIPTION
Silicone flat drainage tube	69449327F N01D01HQ	6mm (6mm×30cm)	N01D016110	551006A	Penrose Silicone Flat Drain ID 6mm L 30CM
		6mm (6mm×50cm)	N01D016210	551106A	Penrose Silicone Flat Drain ID 6mm L 50CM
		8mm (8mm×30cm)	N01D018110	551008A	Penrose Silicone Flat Drain ID 8mm L 30CM
		8mm (8mm×50cm)	N01D018210	551108A	Penrose Silicone Flat Drain ID 8mm L 50CM
		10mm (10mm×30cm)	N01D011110	551010A	Penrose Silicone Flat Drain ID 10mm L 30CM
		10mm (10mm×50cm)	N01D011210	551110A	Penrose Silicone Flat Drain ID 10mm L 50CM
		12mm (12mm×30cm)	N01D012110	551012A	Penrose Silicone Flat Drain ID 12mm L 30CM
		12mm (12mm×50cm)	N01D012210	551112A	Penrose Silicone Flat Drain ID 12mm L 50CM
Silicone Round Perforated Drainage Tube	69449327F N01D03HU	9Fr	N01D030910	554009A	Silicone Tubular Perforated Drain 9Fr 50 cm
		12Fr	N01D031210	554012A	Silicone Tubular Perforated Drain 12Fr 50 cm
		14Fr	N01D031410	554014A	Silicone Tubular Perforated Drain 14Fr 50 cm
		16Fr	N01D031610	554016A	Silicone Tubular Perforated Drain 16Fr 50 cm
		18Fr	N01D031810	554018A	Silicone Tubular Perforated Drain 18Fr 50 cm

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Web: https://www.wellead.com/

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Model	Basic-UDI	Size	WELLLEAD Catalogue Number	Medline REF	DESCRIPTION
Silicone Round Perforated Drainage Tube	69449327F N01D03HU	20Fr	N01D032010	554020A	Silicone Tubular Perforated Drain 20Fr 50 cm
		24Fr	N01D032410	554024A	Silicone Tubular Perforated Drain 24Fr 50 cm
		26Fr	N01D032610	554026A	Silicone Tubular Perforated Drain 26Fr 50 cm
		30Fr	N01D033010	554030A	Silicone Tubular Perforated Drain 30Fr 50 cm
		33Fr	N01D033310	554033A	Silicone Tubular Perforated Drain 33Fr 50 cm
		36Fr	N01D033610	554036A	Silicone Tubular Perforated Drain 36Fr 50 cm
		12Fr	N01E030110	564012A	Silicone Tubular Drains with Collection Bag 100cm Length, 12Fr with 350 ml bag
		14Fr	N01E030210	564014A	Silicone Tubular Drains with Collection Bag 100cm Length, 14Fr with 350 ml bag
		16Fr	N01E030310	564016A	Silicone Tubular Drains with Collection Bag 100cm Length, 16Fr with 350 ml bag
		18Fr	N01E030410	564018A	Silicone Tubular Drains with Collection Bag 100cm Length, 18Fr with 350 ml bag
		20Fr	N01E030510	564020A	Silicone Tubular Drains with Collection Bag 100cm Length, 20Fr with 350 ml bag
		24Fr	N01E030610	564024A	Silicone Tubular Drains with Collection Bag 100cm Length, 24Fr with 350 ml bag
		26Fr	N01E030710	564026A	Silicone Tubular Drains with Collection Bag 100cm Length, 26Fr with 350 ml bag
		30Fr	N01E030810	564030A	Silicone Tubular Drains with Collection Bag 100cm Length, 30Fr with 350 ml bag
		33Fr	N01E030910	564033A	Silicone Tubular Drains with Collection Bag 100cm Length, 33Fr with 350 ml bag
		36Fr	N01E031010	564036A	Silicone Tubular Drains with Collection Bag 100cm Length, 36Fr with 350 ml bag
		12Fr	N01E031110	565012A	Silicone Tubular Drains with Collection Bag 100cm Length, 12Fr with 500 ml bag

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

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Model	Basic-UDI	Size	WELLLEAD Catalogue Number	Medline REF	DESCRIPTION
Silicone Round Perforated Drainage Tube	69449327F N01D03HU	14Fr	N01E031210	565014A	Silicone Tubular Drains with Collection Bag 100cm Length, 14Fr with 500 ml bag
		16Fr	N01E031310	565016A	Silicone Tubular Drains with Collection Bag 100cm Length, 16Fr with 500 ml bag
		18Fr	N01E031410	565018A	Silicone Tubular Drains with Collection Bag 100cm Length, 18Fr with 500 ml bag
		20Fr	N01E031510	565020A	Silicone Tubular Drains with Collection Bag 100cm Length, 20Fr with 500 ml bag
		24Fr	N01E031610	565024A	Silicone Tubular Drains with Collection Bag 100cm Length, 24Fr with 500 ml bag
		26Fr	N01E031710	565026A	Silicone Tubular Drains with Collection Bag 100cm Length, 26Fr with 500 ml bag
		30Fr	N01E031810	565030A	Silicone Tubular Drains with Collection Bag 100cm Length, 30Fr with 500 ml bag
		33Fr	N01E031910	565033A	Silicone Tubular Drains with Collection Bag 100cm Length, 33Fr with 500 ml bag
		36Fr	N01E032010	565036A	Silicone Tubular Drains with Collection Bag 100cm Length, 36Fr with 500 ml bag

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