wellead 维力

Document Nr.: WL-MDR-DOC-042-01-17/B

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:	Extraction Bag
Intended Purpose:	The Extraction Bag is intended to use for removal of resected tissues of abdominal cavity during laparoscopy.
Type/ Size/ Catalogue Number:	Please refer to Table 1
UMDNS Code:	17573
GMDN Code:	56731
EMDN Code:	A99
Basic UDI-DI:	Please refer to Table 1

Classification (MDR, Annex Ⅷ): **IIa, Rule 6**

Conformity Assessment Route: **Quality Management System (Annex IX, Chapter I & III and section 4) + Declaration of Conformity (Annex IV)**

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

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 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/ EN ISO 15223-1:2021/ EN ISO 20417:2021/ EN ISO 10993-1:2020/ EN ISO 10993-5:2009/ 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.02

Expire date of the Certificate: 2028-05-15

Signature:

Name: Chen Yungui

Position: **Management Representative & PRRC**

Place, Date of Issue: **Guangzhou, 2026/07/07**

Table1

Model	Basic-UDI	Size	Wellead REF	Medline REF	Description
Type A	69449327FN01D02HV	200mL	O02A010210	100200A	Med-Lap Extraction Bag Type A 200ml
		400mL	O02A010410	100400A	Med-Lap Extraction Bag Type A 400ml
		800mL	O02A010810	100800A	Med-Lap Extraction Bag Type A 800ml
		1200mL	O02A011212	100900A	Med-Lap Extraction Bag Type A 1200ml
Type C	69449327FO02A03HZ	300mL	O02A030310	110310A	Med-Lap Extraction Bag with Grip Type C 300ml
		550mL	O02A030510	110320A	Med-Lap Extraction Bag with Grip Type C 550ml
		800mL	O02A030810	110380A	Med-Lap Extraction Bag with Grip Type C 800ml
		1200mL	O02A031212	110390A	Med-Lap Extraction Bag with Grip Type C 1200ml
		1600mL	O02A031612	110395A	Med-Lap Extraction Bag with Grip Type C 1600ml

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