wellead 维力

Document Nr.: WL-DOC-042/B

Declaration of Conformity

Manufacturer:	**Well Lead Medical Co., Ltd.** C-4 Jinhu Industrial Estate, Hualong 511434 Panyu, Guangzhou, People Republic of China
European Repre-sentative:	**Shanghai International Holding Corp. GmbH (Europe)** Eiffestrasse 80, 20537 Hamburg, GERMANY
Product Name:	Extraction Bag (Operation Use)
Type or Size:	Type A: 200ml, 400ml, 800ml; Type B: 300ml, 550ml, 800ml; Type C: 300ml, 550ml, 800ml
UMDNS Code:	17573

Classification (MDD, Annex IX): **IIa, Rule 6**

Conformity Assessment Route: **Annex II excluding (4)**

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 Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. The declaration of conformity is issued under our sole responsibility.

DIRECTIVES

General applicable directives: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning Medical devices, amended by Council Directive 2007/47/EC

Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany
Identification number:	CE0123
(EC) Certificate(s):	**G1 038814 0087 Rev.01**
Expire date of the Certificate:	**2024-05-26**
Start of CE Marking:	**2009**
Place, Date of Issue:	**Guangzhou, 2021-02-20**
Signature:	Chen Yungui
Name:	Chen Yun Gui
Position:	**Management Representative**

WELL LEAD 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.welllead.com.cn/

Annex

Article Number	Product Description
0110310	Med-Lap Extraction Bag with Grip 300ml Type C
0110320	Med-Lap Extraction Bag with Grip 550ml Type C
0110380	Med-Lap Extraction Bag with Grip 800ml Type C
100200	Med-Lap Extraction Bag 200ml Type A
100400	Med-Lap Extraction Bag 400ml Type A
100800	Med-Lap Extraction Bag 800ml Type A

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