wellead 维力

Document Nr.: WL-DOC-035/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:	Drainage System
Model or Size:	12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 24Fr, 26Fr, 30Fr, 33Fr, 36Fr
UMDNS Code:	11304

Classification (MDD, Annex IX): **IIa, Rule 7**

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:	**2008**
Place, Date of Issue:	**Guangzhou, 2021-02-20**

Signature:

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	Well Lead's Description
564012	Silicone Drainages 100cm lenght round drains, 12Fr With 350 ml bag
564014	Silicone Drainages 100cm lenght round drains, 14Fr With 350 ml bag
564016	Silicone Drainages 100cm lenght round drains, 16Fr With 350 ml bag
564018	Silicone Drainages 100cm lenght round drains, 18Fr With 350 ml bag
564020	Silicone Drainages 100cm lenght round drains, 20Fr With 350 ml bag
564024	Silicone Drainages 100cm lenght round drains, 24Fr With 350 ml bag
564026	Silicone Drainages 100cm lenght round drains, 26Fr With 350 ml bag
564030	Silicone Drainages 100cm lenght round drains, 30Fr With 350 ml bag
564033	Silicone Drainages 100cm lenght round drains, 33Fr With 350 ml bag
564036	Silicone Drainages 100cm lenght round drains, 36Fr With 350 ml bag
565012	Silicone Drainages 100cm lenght round drains, 12Fr With 500 ml bag
565014	Silicone Drainages 100cm lenght round drains, 14Fr With 500 ml bag
565016	Silicone Drainages 100cm lenght round drains, 16Fr With 500 ml bag
565018	Silicone Drainages 100cm lenght round drains, 18Fr With 500 ml bag
565020	Silicone Drainages 100cm lenght round drains, 20Fr With 500 ml bag
565024	Silicone Drainages 100cm lenght round drains, 24Fr With 500 ml bag
565026	Silicone Drainages 100cm lenght round drains, 26Fr With 500 ml bag
565030	Silicone Drainages 100cm lenght round drains, 30Fr With 500 ml bag
565033	Silicone Drainages 100cm lenght round drains, 33Fr With 500 ml bag
565036	Silicone Drainages 100cm lenght round drains, 36Fr With 500 ml bag

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