wellead 维力

Document Nr.: WL-DOC-045/B

Declaration of Conformity

Manufacturer:	**Well Lead Medical Co., Ltd.**
	C-4 Jinhu Industrial Estate, Hualong 511434 Panyu, Guangzhou, People Republic of China
European Representative:	**Shanghai International Holding Corp. GmbH (Europe)** Eiffestrasse 80, 20537 Hamburg, GERMANY
Product Name:	Silicone Drainage System
Model or Size:	Silicone flat& round drainage tube: 4mmx10mm; 3.5mmx7.5mm Silicone flat drainage tube: 6mm, 8mm, 10mm, 12mm; Silicone Round Perforated Drainage Tube: 9Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 24Fr, 26Fr, 28Fr, 30Fr, 33Fr, 36Fr Silicone drainage jar: 100ml, 150ml, 200ml
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:	**2009**
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

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Tel: +86 20 84758878
Web: http://www.welllead.com.cn/

Annex

Article Number	Product Description
551006	Silicone capillary drain soft 6mm, 30cm long
551008	Silicone capillary drain soft 8mm, 30cm long
551010	Silicone capillary drain soft 10mm, 30cm long
551012	Silicone capillary drain soft 12mm, 30cm long
551106	Silicone capillary drain soft 6mm, 50cm long
551108	Silicone capillary drain soft 8mm, 50cm long
551110	Silicone capillary drain soft 10mm, 50cm long
551112	Silicone capillary drain soft 12mm, 50cm long
554009	Silicone Drainages 50 cm lenght round drains
554012	Silicone Drainages 50 cm lenght round drains
554014	Silicone Drainages 50 cm lenght round drains
554016	Silicone Drainages 50 cm lenght round drains
554018	Silicone Drainages 50 cm lenght round drains
554020	Silicone Drainages 50 cm lenght round drains
554024	Silicone Drainages 50 cm lenght round drains
554026	Silicone Drainages 50 cm lenght round drains
554030	Silicone Drainages 50 cm lenght round drains
554033	Silicone Drainages 50 cm lenght round drains
554036	Silicone Drainages 50 cm lenght round drains

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