

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: All Silicone Foley Catheter

Model or Size: Refer to Annex

GMDN Code: 34917

Classification (MDD, Annex IX): **IIb, Rule 5**

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

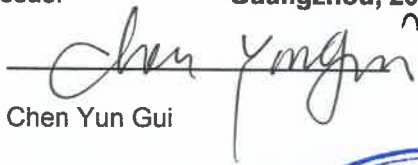
(EC) Certificate(s): **G1 038814 0079 Rev. 00**

Expire date of the Certificate: **2024-05-26**

Start of CE Marking: **2005**

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

Signature:



Name: Chen Yun Gui

Position: **Management Representative**



Annex

Model	Type	Size
Silicone Foley Catheter	2-way Paediatric	6Fr/ 8Fr/ 10Fr
	2-way Female	12Fr/ 14Fr/ 16Fr/ 18Fr/ 20Fr/ 22Fr/
	2-way Standard	24Fr/ 26Fr
	3-way Female 3-way Standard	16Fr/ 18Fr/ 20Fr/ 22Fr/ 24Fr/ 26Fr
Hydrophilic Silicone Foley Catheter	2-way Paediatric	6Fr/ 8Fr/ 10Fr
	2-way Female	12Fr/ 14Fr/ 16Fr/ 18Fr/ 20Fr/ 22Fr
	2-way Standard	
	3-way Female 3-way Standard	16Fr/ 18Fr/ 20Fr/ 22Fr
	accessory	Water sachet
Tiemann tip Silicone Foley Catheter	2-way	12Fr/ 14Fr/ 16Fr/ 18Fr/ 20Fr/ 22Fr/ 24Fr/ 26Fr
Couvelaire/ Dufour / Mercier tip Silicone Foley Catheter	2-way	16Fr/ 18Fr/ 20Fr/ 22Fr/ 24Fr
	3-way	16Fr/ 18Fr/ 20Fr/ 22Fr/ 24Fr