

## 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 : Latex Foley Catheter

Type 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: **2003**

Place, Date of Issue: **Guangzhou, 2020-03-31**

Signature: \_\_\_\_\_

Name:

Chen Yun

Position:

Management Representative



**Annex**

<b>Model</b>	<b>Type</b>	<b>Size</b>
Latex Foley Catheter	2-way, paediatric	6Fr, 8Fr, 10Fr
	2-way, standard	12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr, 28Fr, 30Fr
	2-way, female	12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr
	2-way, Tiemann tip	12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr
	3-way	16Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr
Hydrophilic Latex Foley Catheter	2-way, paediatric	6Fr, 8Fr, 10Fr
	2-way, standard	12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr
	2-way, female	12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr
	2-way, Tiemann tip	12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr
	3-way	16Fr, 18Fr, 20Fr, 22Fr