

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

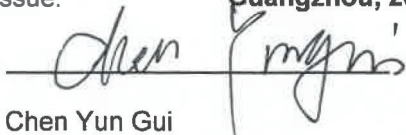
Identification number: CE0123

(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, 2021-02-20**

Signature: 

Name: Chen Yun Gui

Position: **Management Representative**



Annex

Model	Type	Size
Latex Fo- ley Cathe- ter	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 Fo- ley Cathe- ter	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
	accessory	Water sachet

Annex

Article Number	Product Description
661006	Latex Foley Catheter, 2 Way Nelaton 6FR 3ml, plastic valve
661008	Latex Foley Catheter, 2 Way Nelaton 8FR 3-5ml, plastic valve
661010	Latex Foley Catheter, 2 Way Nelaton 10FR 3-5ml, plastic valve
662012	Latex Foley Catheter, 2 Way Nelaton 12FR 5-10ml, plastic valve
662014	Latex Foley Catheter, 2 Way Nelaton 14FR 5-10ml, plastic valve
662016	Latex Foley Catheter, 2 Way Nelaton 16FR 5-10ml, plastic valve
662018	Latex Foley Catheter, 2 Way Nelaton 18FR 5-10ml, plastic valve
662020	Latex Foley Catheter, 2 Way Nelaton 20FR 5-10ml, plastic valve
662022	Latex Foley Catheter, 2 Way Nelaton 22FR 5-10ml, plastic valve
662024	Latex Foley Catheter, 2 Way Nelaton 24FR 5-10ml, plastic valve
662026	Latex Foley Catheter, 2 Way Nelaton 26FR 5-10ml, plastic valve
662212	Latex Foley Catheter, 2 Way Nelaton 12FR 5-10ml, rubber valve
662214	Latex Foley Catheter, 2 Way Nelaton 14FR 5-10ml, rubber valve
662216	Latex Foley Catheter, 2 Way Nelaton 16FR 5-10ml, rubber valve
662218	Latex Foley Catheter, 2 Way Nelaton 18FR 5-10ml, rubber valve
662220	Latex Foley Catheter, 2 Way Nelaton 20FR 5-10ml, rubber valve
662222	Latex Foley Catheter, 2 Way Nelaton 22FR 5-10ml, rubber valve
662224	Latex Foley Catheter, 2 Way Nelaton 24FR 5-10ml, rubber valve
662226	Latex Foley Catheter, 2 Way Nelaton 26FR 5-10ml, rubber valve
663012	Latex Foley Catheter, 2 Way Nelaton 12FR 30ml, plastic valve
663014	Latex Foley Catheter, 2 Way Nelaton 14FR 30ml, plastic valve
663016	Latex Foley Catheter, 2 Way Nelaton 16FR 30ml, plastic valve
663018	Latex Foley Catheter, 2 Way Nelaton 18FR 30ml, plastic valve
663020	Latex Foley Catheter, 2 Way Nelaton 20FR 30ml, plastic valve
663022	Latex Foley Catheter, 2 Way Nelaton 22FR 30ml, plastic valve
663024	Latex Foley Catheter, 2 Way Nelaton 24FR 30ml, plastic valve
663026	Latex Foley Catheter, 2 Way Nelaton 26FR 30ml, plastic valve
665012	Latex Foley Catheter, 2 Way Tiemann 12FR 5-10ml, plastic valve
665014	Latex Foley Catheter, 2 Way Tiemann 14FR 5-10ml, plastic valve
665016	Latex Foley Catheter, 2 Way Tiemann 16FR 5-10ml, plastic valve
665018	Latex Foley Catheter, 2 Way Tiemann 18FR 5-10ml, plastic valve
665020	Latex Foley Catheter, 2 Way Tiemann 20FR 5-10ml, plastic valve
666012	Latex Foley Catheter, 2 Way Tiemann 12FR 30ml, plastic valve
666014	Latex Foley Catheter, 2 Way Tiemann 14FR 30ml, plastic valve
666016	Latex Foley Catheter, 2 Way Tiemann 16FR 30ml, plastic valve
666018	Latex Foley Catheter, 2 Way Tiemann 18FR 30ml, plastic valve
666020	Latex Foley Catheter, 2 Way Tiemann 20FR 30ml, plastic valve
668016	Latex Foley Catheter, 3 Way Nelaton 16FR 30ml, plastic valve
668018	Latex Foley Catheter, 3 Way Nelaton 18FR 30ml, plastic valve

668020	Latex Foley Catheter, 3 Way Nelaton 20FR 30ml, plastic valve
668022	Latex Foley Catheter, 3 Way Nelaton 22FR 30ml, plastic valve
668024	Latex Foley Catheter, 3 Way Nelaton 24FR 30ml, plastic valve
668026	Latex Foley Catheter, 3 Way Nelaton 26FR 30ml, plastic valve