

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: Suprapubic Catheter Set

Model or Size: Suprapubic Catheter, Puncture Set, Exchange Set

UMDNS Code: 10751

Classification (MDD, Annex IX): **Ila, 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: **2021-02-19**

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

Signature: _____

Chen Yun Gui

Name: Chen Yun Gui

Position: **Management Representative**



Annex

Article Number	Product Description
645006	Silicone Foley Catheter, 2 Way Nelaton 6FR 1.5ml Open End
645008	Silicone Foley Catheter, 2 Way Nelaton 8FR 3ml Open End
645010	Silicone Foley Catheter, 2 Way Nelaton 10FR 3-5ml Open End
645012	Silicone Foley Catheter, 2 Way Nelaton 12FR 5-10ml Open End
645014	Silicone Foley Catheter, 2 Way Nelaton 14FR 5-10ml Open End
645016	Silicone Foley Catheter, 2 Way Nelaton 16FR 5-10ml Open End
645018	Silicone Foley Catheter, 2 Way Nelaton 18FR 5-10ml Open End
645020	Silicone Foley Catheter, 2 Way Nelaton 20FR 5-10ml Open End
645022	Silicone Foley Catheter, 2 Way Nelaton 22FR 5-10ml Open End
645024	Silicone Foley Catheter, 2 Way Nelaton 24FR 5-10ml Open End
645026	Silicone Foley Catheter, 2 Way Nelaton 26FR 5-10ml Open End