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Document Nr.: WL-DOC-167/A

Declaration of Conformity

Manufacturer:	**Well Lead Medical Co., Ltd.** C-4 Jinhu Industrial Estate, Hualong 511434 Panyu, Guangzhou, People Republic of China
European Repre-sentative:	**Shanghai International Holding Corp. GmbH (Europe)** Eiffestraße 80, 20537 Hamburg, GERMANY
Product Name:	Suprapubic Catheter Set
Model or Size:	Suprapubic Catheter
UMDNS Code:	10751
Catalogue Number:	Table 1

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:	**2021-02-19**
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

Add: C-4# Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, P.R. China
Tel : +86 20 84758878
Web: http://www.welllead.com.cn/

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Table1 Catalogue Number

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

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