wellead 维力

Document Nr.: WL-DOC-001-01/A

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**

WELL LEAD MEDICAL CO. LTD. 广州维力医疗器械股份有限公司

Annex

Model	Type	Size
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
	accessory	Water sachet

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

Annex

Article Number	Product Description
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

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Well Lead Medical Co., Ltd.
C-4 Jinhu Industrial Estate
Hualong Panyu
Guangzhou
Guangdong
511434
China

23 May 2024

Notified Body Confirmation Letter
Reference: EU2023-607/874023

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Well Lead Medical Co., Ltd.
C-4 Jinhu Industrial Estate
Hualong Panyu
Guangzhou
Guangdong
511434
China

SRN Number (if available): CN-MF-000006728

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

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Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Latex Foley Catheter	Class IIb excluding Class IIb implantable non-WET	N/A	#G1 038814 0079 REV. 00 NB# 0123
All Silicone Foley Catheter	Class IIb excluding Class IIb implantable non-WET	N/A	#G1 038814 0079 REV. 00 NB# 0123
Prefilled syringe with purified water or glycerin solution	Class I device placed on the market in sterile condition	N/A	#G1S 038814 0090 Rev. 01 NB# 0123
Spigot	Class I device placed on the market in sterile condition	N/A	#G1S 038814 0090 Rev. 01 NB# 0123
Urine Meter	Class I device placed on the market in sterile condition Class I device with a measuring function	N/A	#G2MS 18 03 38814 069 NB# 0123
Urine Bag	Class I device placed on the market in sterile condition	N/A	#G1S 038814 0089 Rev. 00 NB# 0123

Confirmation Letter Revision History

Date	Action
2024/05/23	Initial issue

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