EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 801167 R000

Manufacturer: Well Lead Medical Co., Ltd.

Address:
C-4 Jinhu Industrial Estate
Hualong Panyu
Guangzhou
Guangdong
511434
China

Single Registration Number: CN-MF-000006728

EU Authorised Representative: Shanghai International Holding Corp. GmbH (Europe)

Address:
Eiffestrasse 80
Hamburg
20537
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2023-12-14**

Current Issue Date: **2025-03-07**

Starting Validity Date: **2025-03-07**

Expiry Date: **2028-12-13**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Latex Foley Catheter	Latex Foley Catheter is inserted into the bladder through urethra and are indicated for routine urine drainage or for routine post-operative drainage and irrigation bladder.
All Silicone Foley Catheter	All Silicone Foley Catheter is intended to be used by trained person or healthcare professionals for transurethral or suprapubic drainage. The 3-way model can be used for irrigation of the bladder.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-12-14	30056657	Issued
Current	30380181	Amended – Update to the intended purpose for All Silicone Foley Catheter

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