EU Quality Management System Certificate

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

MDR 776669 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 Medical Devices

First Issue Date: **2022-12-19**

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

Starting Validity Date: **2023-12-14**

Expiry Date: **2027-12-18**

...making excellence a habit.™

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.
A Member of the BSI Group of Companies.

EU Quality Management System Certificate

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

MDR 776669 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Drainage and fluids collection devices (Urine Meter)	Class Im & Is
Drainage and fluids collection devices (Urine Bag)	Class Is
Syringes (Prefilled syringe with purified water or glycerin solution; empty syringe)	Class Is
Adapters, Connectors, Ramps, Stopcocks, Caps (Cap, Spigot)	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions. For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.	

First Issue Date: **2022-12-19**

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

Starting Validity Date: **2023-12-14**

Expiry Date: **2027-12-18**

...making excellence a habit.™

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.
A Member of the BSI Group of Companies.

EU Quality Management System Certificate

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

MDR 776669 R000

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
2022-12-19	3736457	Issued
Current	30009608	Supplemented – Addition of Is Device (Urine Bag) Amended – Addition of subcontractors relating to sterilization and manufacturing for Urine Bag and Urine Meter

First Issue Date: **2022-12-19**

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

Starting Validity Date: **2023-12-14**

Expiry Date: **2027-12-18**

...making excellence a habit.™

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.
A Member of the BSI Group of Companies.