

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Fortune Medical Instrument Corp.  
6F, No. 29, Sec. 2  
Jhongjheng E. Rd.  
Danshuei Dist.  
New Taipei City  
251  
Taiwan

Holds Certificate Number:

**MD 588797**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture and sales of sterile urological catheters and accessories, catheter spigot, drainage tube and accessories, endotracheal tube, tracheostomy tube, reservoir, epistaxis device, gastrointestinal tube, implantable vascular access port and accessories, silicone surgical ruler, silicone vessel ID loops and silicone clamp jaw cover, and of non-sterile laryngeal mask tube, resuscitator and accessories, vacuum suction and accessories, tracheal tube fixation device, scar management products, silicone stool drain system, catheter fixation device and skin protector- spray.

The provision of ethylene oxide sterilization services in accordance with EN ISO 11135:2014.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2012-08-23

Latest Revision Date: 2022-08-01

Effective Date: 2022-08-09

Expiry Date: 2025-08-08

Page: 1 of 2



...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.  
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory).  
Printed copies can be validated at [www.bsigroup.com/ClientDirectory](https://www.bsigroup.com/ClientDirectory)

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP, Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.