

# Certificate of Registration

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

This is to certify that:

Lagis Enterprise Co., Ltd.  
No. 29, Gong 1st Rd.  
Dajia Dist.  
Taichung City  
437  
Taiwan

Holds Certificate Number:

**MD 685052**

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 and manufacture of surgical device, including sterile laparoscopy insufflators, sterile laparoscopic surgical accessories, irrigation pump, sterilization pouches, sterile surgical drapes and sterile and non-sterile electro-surgical cutting and coagulation devices with accessories.

The provision of maintenance services for surgical device, including irrigation pump, surgical instrument, electrode devices.

For and on behalf of BSI:

\_\_\_\_\_  
Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2018-06-07

Latest Revision Date: 2021-10-28

Effective Date: 2020-11-08

Expiry Date: 2023-11-07

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Certificate No: **MD 685052**

Location

Registered Activities

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Lagis Enterprise Co., Ltd.  
No. 29, Gong 1st Rd.  
Dajia Dist.  
Taichung City  
437  
Taiwan

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The manufacture of surgical device, including sterile laparoscopy insufflators, sterile laparoscopic surgical accessories, irrigation pump, sterilization pouches, sterile surgical drapes and sterile and non-sterile electro-surgical cutting and coagulation devices with accessories. The provision of maintenance services for surgical device, including irrigation pump, surgical instrument, electrode devices.

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Lagis Enterprise Co., Ltd.  
No. 24, Gong 1st Rd.  
Dajia Dist.  
Taichung City  
437  
Taiwan

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The design of surgical device, including sterile laparoscopy insufflators, sterile laparoscopic surgical accessories, irrigation pump, sterilization pouches, sterile surgical drapes and sterile and non-sterile electro-surgical cutting and coagulation devices with accessories.

Original Registration Date: 2018-06-07

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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](#).  
Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

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