

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 588902
Issued To: Fortune Medical Instrument Corp
6F., No. 29, Sec. 2, Jhongjheng E.Rd.,
Danshuei Dist,
New Taipei City
251
Taiwan

In respect of:

The design, manufacture and final inspection of sterile urological catheters and accessories, drainage tube and accessories, endotracheal tube, tracheostomy tube, reservoir, gastrointestinal tube and accessories, silicone surgical ruler and silicone vessel ID loops and non-sterile laryngeal mask tube.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: 2012-08-27

Date: 2018-10-05

Expiry Date: 2023-09-24

...making excellence a habit.™

Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

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 BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 588902**
Date: **2018-10-05**
Issued To: **Fortune Medical Instrument Corp**
6F., No. 29, Sec. 2, Jhongjheng E.Rd.,
Danshuei Dist,
New Taipei City
251
Taiwan



Subcontractor:	Service(s) supplied
Fortune Medical Instrument Corp No. 256, Changchun 2nd Road Jhongli Dist Taoyuan City 320 Taiwan	Design ETO Sterilization Final Inspection Manufacture Regulatory Compliance
PRIM S.A. C/F 15, Pol. Ind. No.1 28938 Mostoles Madrid Spain	EU Representative

...making excellence a habit.™



EC Certificate - Full Quality Assurance System Certificate History

Certificate No: CE 588902
Date: 2018-10-05
Issued To: Fortune Medical Instrument Corp
 6F., No. 29, Sec. 2, Jhongjheng E.Rd.,
 Danshuei Dist,
 New Taipei City
 251
 Taiwan

Date	Reference Number	Action
27 August 2012	7859139	First-issue. Transfer from another Notified Body, TÜV SÜD, certificate reference G1 11 06 65095 006.
01 October 2013	8063652	Certificate renewal.
Current	9642053	Amendment to scope to add in "and accessories" for sterile urological catheters, "and accessories" for sterile drainage tube, addition of sterile Silicone surgical ruler, sterile Silicone vessel ID loops. Administrative changes to the address for the head office and the subcontractor, Fortune Medical Instrument Corp, No 256, Changchun 2nd Road. Removal of vacuum suction and resuscitator. Certificate renewal.

...making excellence a habit.

Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
 This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PR. 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 BSI Group of Companies.

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 No: **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 and implantable vascular access port and accessories, silicone surgical ruler and silicone vessel ID loops, and of non-sterile laryngeal mask tube, resuscitator and accessories, vacuum suction and accessories, tracheal tube fixation device and scar management products.
The provision of ethylene oxide sterilization services in accordance with EN ISO 11135:2014.

For and on behalf of BSI:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2012-08-23

Latest Revision Date: 2019-07-31

Effective Date: 2019-08-09

Expiry Date: 2022-08-08

Page: 1 of 2



...making excellence a habit.™

Certificate No: **MD 588797**

Location

Registered Activities

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

The sales of sterile urological catheters and accessories, catheter spigot, drainage tube and accessories, endotracheal tube, tracheostomy tube, reservoir, epistaxis device, gastrointestinal tube and implantable vascular access port and accessories, silicone surgical ruler and silicone vessel ID loops, and of non-sterile laryngeal mask tube, resuscitator and accessories, vacuum suction and accessories, tracheal tube fixation device and scar management products. The sales of ethylene oxide sterilization services in accordance with EN ISO 11135:2014.

Fortune Medical Instrument Corp.
No. 256, Changchun 2nd Rd.
Jhongli Dist.
Taoyuan City
320
Taiwan

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 and implantable vascular access port and accessories, silicone surgical ruler and silicone vessel ID loops, and of non-sterile laryngeal mask tube, resuscitator and accessories, vacuum suction and accessories, tracheal tube fixation device and scar management products. The provision of ethylene oxide sterilization services in accordance with EN ISO 11135:2014.

Original Registration Date: 2012-08-23

Effective Date: 2019-08-09

Latest Revision Date: 2019-07-31

Expiry Date: 2022-08-08

Page: 2 of 2

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.bsi-global.com/ClientDirectory or telephone +886 (02)2656-0333.

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.