

SILICONE FOLEY BALLOON CATHETER

Fortune® Silicone 3-Way Foley Catheter Features:

- 100% medical grade silicone for superior biocompatibility.
- Transparent tube with X-ray opaque line.
- A soft and uniformly inflated balloon makes the tube sit well against the bladder.
- 3-Way design with an attached plug on the irrigation funnel.
- Tapered Central funnel could be connected with irrigation bags.
- Includes an individual sterilized packed Catheter Spigot.
- Sterilized double packaging.
- The tip of 3-way Foley Balloon Catheter with open hole, it could be used together with guide wire for difficulty in catheterization.

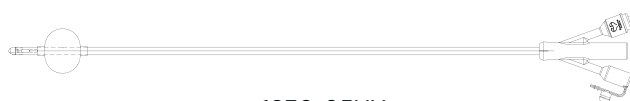
A Silicone 3-Way Foley Balloon



SPECIFICATIONS

3-Way Foley Balloon Catheter

REF. No.	Size	Balloon	Length	Description
1830-0514	14 FR			
1830-0516	16 FR			
1830-0518	18 FR			Attached plug on flushing port
1830-0520	20 FR	20-30 cc/ml	420 mm	X-ray opaque line
1830-0522	22 FR			Catheter spigot
1830-0524	24 FR			
1830-0526	26 FR			



1830-05XX

EC Certificate - Full Quality Assurance System

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

No.

CE 588902

Issued To:

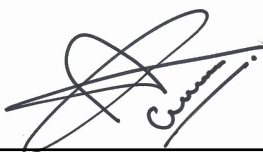
**Fortune Medical Instrument Corp
6F., No. 29, Sec. 2, Jhongjheng E.Rd.,
Danshuei Dist,
New Taipei City
251
Taiwan**

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 2797):



Albert Roossien, Regulatory Lead

First Issued: **2012-08-27**

Date: **2019-02-25**

Expiry Date: **2023-09-24**

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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.

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: **2019-02-25**
 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

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EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 588902**
Date: **2019-02-25**
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.
05 October 2018	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.
Current	7932553	Traceable to NB 0086.

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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, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.**CE 589950****Issued To:**

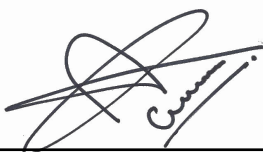
**Fortune Medical Instrument Corp
6F., No. 29, Sec. 2, Jhongjheng E.Rd.,
Danshuei Dist,
New Taipei City
251
Taiwan**

In respect of:

Those aspects of Annex V concerned with securing and maintaining sterile conditions in the manufacture of sterile epistaxis device and catheter spigot.

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

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



Albert Roossien, Regulatory Lead

First Issued: **2012-08-27**

Date: **2019-02-25**

Expiry Date: **2023-09-24**

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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.

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No: **CE 589950**
 Date: **2019-02-25**
 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
 320 Jhongli City
 Taoyuan County
 Taiwan

ETO Sterilization
Final Inspection
Manufacture
Regulatory Compliance

PRIM S.A.
 C/F 15, Pol. Ind. No.1
 28938 Mostoles
 Madrid
 Spain

EU Representative

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EC Certificate - Production Quality Assurance

Certificate History

Certificate No: **CE 589950**
Date: **2019-02-25**
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 G2S 11 06 65095 007.
01 October 2013	8063654	Certificate renewal.
25 September 2018	9642055	Administrative change to the address for the head office and the subcontractor, Fortune Medical Industrial Corp, No. 256 Changchun 2 nd Road. Renewal.
Current	7932553	Traceable to NB 0086.

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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, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

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

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

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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, Kilmarnock, 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.

bsi.



By Royal Charter

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



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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 <https://www.bsi-global.com/ClientDirectory>
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, Knowlton, Milton Keynes MK5 8PP Tel: +44 345 080 9000
BSI Administration UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W1 1AL, UK.
A Member of the BSI Group of Companies.