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):

Digitally signed by Iarovoi Petru
Date: 2021.12.30 11:36:50 EET
Reason: MoldSign Signature
Location: Moldova

Albert Roossien, Regulatory Lead

First Issued: **2012-08-27** Date: **2019-02-25** Expiry Date: **2023-09-24**

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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.

By Royal Charter

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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By Royal Charter

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.

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
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By Royal Charter

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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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.

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BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

By Royal Charter

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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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
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A member of BSI Group of Companies.

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 2nd Road. Renewal.
Current	7932553	Traceable to NB 0086.

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.

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