By Royal Charter

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

Digitally signed by Bunic Gheorghe
Date: 2023.12.03 12:24:23 EET
Reason: MoldSign Signature
Location: Moldova

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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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**

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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.

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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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2012-08-27** Date: **2018-09-25** Expiry Date: **2023-09-24**

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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:	**2018-09-25**
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	**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 - Production Quality Assurance Certificate History

Certificate No: **CE 589950**

Date: **2018-09-25**

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.
Current	9642055	Administrative change to the address for the head office and the subcontractor, Fortune Medical Industrial Corp, No. 256 Changchun 2nd Road. Renewal.

X-MED MEDICAL DEVICES	**DICHIARAZIONE DI CONFORMITÁ** ***DECLARATION OF CONFORMITY***	**Data: 06/07/2023** **Rev. 11**

Fabbricante: *Manufacturer:*	**X-MED S.r.l.** Via Statale Sud, 113 - 41037 Mirandola (MO) - ITALY
Dispositivo Medico: *Medical Device:*	**TRACHEO SET**
Descrizione: *Description:*	Dispositivo medico sterile, monouso per tracheostomia percutanea dilatativa. *Sterile, single-use medical device for percutaneous dilatative tracheostomy.*
Destinazione d'uso: *Intended use:*	Destinato ad essere utilizzato in procedure di tracheostomia percutanea dilatativa in ambito di Anestesia e Rianimazione. *Intended for use in percutaneous dilated tracheostomy procedures in Intensive Care Units.*
Classificazione Allegato IX: *Classification Annex IX:*	**Classe IIa** (Regola 7 della DDM 93/42/CEE) *Class IIa (Rule 7 MDD 93/42/EEC)*
Percorso di certificazione: *Certification route:*	**Allegato II** della DDM 93/42/CEE *Annex II of the MDD 93/42/EEC*

X-MED S.r.l. dichiara, sotto la propria responsabilità, che il Dispositivo Medico sopra menzionato è conforme ai Requisiti Essenziali della Direttiva Dispositivi Medici 93/42/CEE e s.m.i.. Il Fascicolo Tecnico contenente la documentazione pertinente è conservato presso il Fabbricante e messo a disposizione delle Autorità Competenti e dell'Ente Notificato. X-MED S.r.l. ha sviluppato una procedura per la sorveglianza post-vendita in accordo al Regolamento MDR 2017/745 ed è la sola responsabile della presente Dichiarazione di Conformità.

X-MED S.r.l. declares, under its own responsibility, that the above, mentioned Medical Device is conforming to the essential requirements of the Medical Device Directive 93/42/CEE and subsequent amendments. Technical File and supporting documentation are retained under the premises of the Manufacturer at disposition of the Competent Authorities and Notified Body. The manufacturer is the only responsible for this Declaration of Conformity. X-MED S.r.l. has developed an internal procedure for post-market surveillance of the medical devices according to Regulation MDR 2017/745 and is the sole responsibility of this Declaration of Conformity.

Direttive e Leggi applicabili
Applicable Directives and Laws

- D.Lgs. 46/97 emendato con il D. Lgs 37/10 quale recepimento in Italia della DDM
  D.Lgs. 46/97 amended by D. Lgs 37/10 as transposition in Italy of DDM
- Direttiva CEE 93/42 sui dispositivi medici e s.m.i.
  Council Directive 93/42/EEC and subsequent amendments

Norme europee armonizzate applicabili
Applicable harmonised European standards

L'elenco delle norme applicabili è riportato nel Capitolo 15 del corrispondente Fascicolo Tecnico FT - 04
The list of applicable standards is reported at Chapter 15 of the correspondent Technical File FT - 04.

La presente dichiarazione di conformità è valida fino alla scadenza del certificato CE rilasciato dall'Ente Notificato. Sul certificato di rilascio del prodotto finito il Fabbricante richiama la presente Dichiarazione di Conformità.
The present Declaration of Conformity is valid until the expiry date of CE Certificate released by the Notification Body. It is mentioned also in the release Certificate of finished products issue by the Manufacturer.

XMED MEDICAL DEVICES	**DICHIARAZIONE DI CONFORMITÁ** ***DECLARATION OF CONFORMITY***	**Data: 06/07/2023** **Rev. 11**

Ente Notificato: *Notified Body:*	**KIWA CERMET ITALIA SPA** *Via Cadriano, 23* *40057 Granarolo dell 'Emilia (BO)*	Nr. Ente Notificato: *Nr. Notified Body:*	0476
Certificato Nr.: *Certificate Nr.:*	MED 31136	Data primo rilascio: *First issue date:*	07/05/2013
Valido da: Valid from:	28/06/2018	Ultima modifica Last change date:	28/04/2021 Rev. 7
Scadenza: *Expiry date:*	06/05/2023	Scadenza dichiarazione: *Expiry Declaration:*	06/05/2023

Allegato 1: Elenco codici di vendita e CND / GMDN
(Annex 1: List of codes for sale and CND / GMDN)

Codice (*Codes*) REF	Descrizione (Description)	CND*	GMDN**
600/600XXD 600/600XXDD	Dispositivo medico sterile monouso composto da strumenti chirurgici, medicazioni, tamponi, siringhe, dilatatori, tubi per tracheostomia e altri componenti utilizzati per eseguire procedure di tracheostomia percutanea dilatativa. *Sterile, single-use medical device consisting of surgical instruments, dressings, swabs, syringes, dilators, tracheostomy tubes and other components used to perform percutaneous dilatative tracheostomy procedures.*	R010699	14099

* CND = Classificazione Nazionale italiana dei Dispositivi medici
** GMDN = Global Medical Device Nomenclature

Mirandola, 06/07/2023

Legale Rappresentante
Legal Representative

La presente dichiarazione di conformità è valida fino alla scadenza del certificato CE rilasciato dall'Ente Notificato. Sul certificato di rilascio del prodotto finito il Fabbricante richiama la presente Dichiarazione di Conformità.
The present Declaration of Conformity is valid until the expiry date of CE Certificate released by the Notification Body. It is mentioned also in the release Certificate of finished products issue by the Manufacturer.