Digitally signed by Bunic Gheorghe
Date: 2022.11.23 17:32:56 EET
Reason: MoldSign Signature
Location: Moldova

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

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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By Royal Charter

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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ISO 9001 BUREAU VERITAS Certification

ISO 13485 BUREAU VERITAS Certification

CERTIFICATION
DECLARATION OF CE CONFORMITY – Directive 93/42/CE

BOLSAPLAST S.L., supplies under CE mark, the following products:

- Paper/Film Flat Bags (MBO)
- Paper/Film Selfsealing Bags (MBA)
- Paper/Film Gusset Bags (MBF)
- Paper/Film Flat Reels (MRP)
- Paper/Film Gusset Reels (MRF)
- Tyvek®/Film Flat Bags (MBT)
- Tyvek®/Film Flat Reels (MRT)
- Steam Tape (MCV)
- Bolsacrepe (MCREP)
- Bolsacover (MBCOVER)

All our products are adequate for hospital using, in sterilization processes of medical-surgical products and similar materials.

Products above mentioned are produced in conformity with EN 868-2/3/4/5 and ISO 11607-1, about packaging and systems for medical products to be sterilized.

Our products meet essential requirements in Annex I of the EEC/93/42 Directive and they belong to Class 1 non sterile packaging.

According to our quality system, all necessary processes are took to agree with manufacturing and service parameters established by our quality management system under norm ISO 9001-2008 and ISO13485-2013. Surveillance process and technical information are developed to also agree with norms.

Signature : Jaume Pares Criville
Date : 31st March 2017

bolsaplast
BOLSAPLAST, S.L. - CIF: B-08808990
Domicilio Fiscal: C/ BERNAT METGE, 110-112
Correspondencia: C/ BERNAT METGE, 112
08205 - SABADELL (Barcelona) SPAIN
Tel.: 34 93 711 73 61 - Fax: 34 93 712 23 55

CERTIFICATE

kiwa

Reg. Numero / *Reg. Number*	MED 31136	Revisione / *Revision*	5
Primo rilascio / *First issue date*	2013-05-07	Valido da / *Valid from*	2018-06-28
Scadenza / *Valid until*	2023-05-06	Ultima modifica / *Last change date*	2019-03-20

Certificato CE del Sistema di Garanzia della Qualità
EC Quality Assurance System Certificate

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema completo di garanzia di Qualità dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the full Quality Assurance System of the Organization:*

X-Med S.r.l.

Sede Legale e Operativa / *Registered and operational headquarter:*
Via Statale Sud, 113/B
41037 Mirandola, MO - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato II escluso il pto 4, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici/ *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex II without point 4, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Guaine sterili per endoscopi rigidi e flessibili / *Sterile covers for flexible and rigid endoscopes*
Kit chirurgici sterili per tracheostomia / *Sterile surgical kit for tracheostomy*
Kit per manipolazione uterina / *Kit for uterine manipulation*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel. +39.051.4588.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET

Rif. rapporto di audit/ *Ref. audit report:* del/dated 02/03-05-2018

Chief Operating Officer
Giampiero Belcredi

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

Ackermann Instrumente GmbH
Eisenbahnstraße 65 - 67
78604 Rietheim-Weilheim
Germany

for the scope

**Devices for Endoscopy, Scopes, Cannulas,
Suction and Irrigation Systems, Shaver- Systems
(see attachment)**

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

Annex II – excluding Section 4
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2020-07-10
Valid until	2024-05-26
Registration no.	D1458100002
Report no.	P20-00999-178914
Stuttgart	2020-07-10

Head of Certification Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-246.10.06

mdc medical device certification GmbH
Kriegerstraße 6
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Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de