Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. ..... din .....

Solicitantul Ericon S.R.L._, cu sediul _Durlesti, V. Lupu 6 ,tel./fax: +373 22 52 01 08 ,+373 79 41 00 42, e-mail bunicgh@gmail.com,

solicit actualizarea Etichetei si Instructiunilor de utilizare în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

-Fortune Medical Instrument Corp (Thoracic Drain Tube)
-Fortune Medical Instrument Corp (Endotracheal Tube)

Data _____ Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: Ericon S.R.L., cu sediul Durlesti, V. Lupu 6,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

-Fortune Medical Instrument Corp (Thoracic Drain Tube)
-Fortune Medical Instrument Corp (Endotracheal Tube)

Sunt autentice și corespund realității.

Gheorghe Bunic *Semnătura* _____

Data _____

fortune
medical

Letter of Authorization

We, FORTUNE MEDICAL INSTRUMENT CORP.

based in 6 Fl, No. 29, Sec. 2, JhongJheng E. Road. Danshuei Dist, New Taipei City 251, Taiwan

Tel: 886-2-2624-2233 Fax: 886-2-2624-2266

Here by glad to assign ERI CON SRL, based in 6,Vasile Lupu str. Durlești. Republic of Moldova,

as our authorized representative in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC or 90/385/EEC and act as Fortune's non-exclusive distributor in Republic of Moldova for two years, item details as below:

Designation	Re f rences
Silicone 2-way & 3-way Foley Balloon catheter	1821-05** / 1822-05** / 1823-05** / 1830-05** / 4822-05** /
Silicone Hematuria Catheter.	1861-03** / 1862-03** / 1863-03** / 1864-03**/ 1865-03**
Silicone Endotracheal Tube	1510-****/ 1540-****/ 1545-****/ 1550-****/ 1555-****
Silicone Tracheostomy Tube	1561-****/ 1560-****/ 1565-****
Silicone Stomach (Gastric) Tube	2020-00**
Silicone Nasal Epistaxis Balloon	3101-0830/ 3102-2010/ 3103-0930

We declare that the company mentioned above is authorized to promoting, training, selling, participating in tenders, after-sales-service and register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova, and to perform Essential Duties required by Law No. 102 09.06.2017 regarding medical devices.

Signature:

Name: Sam Wang

Position: Vice President & Marketing Director

Date: SEP 18 2020

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 catheter sets, drainage tube sets, endotracheal tube, tracheostomy tube, gastrointestinal tubes, silicone surgical ruler and silicone vessel ID loops;
The design, manufacture and final inspection of non-sterile birth-vac cup, laryngeal mask tube and manual resuscitator sets.
Those aspects concerned with securing and maintaining sterile conditions in the manufacture of closed wound vacuum reservoir, collection bag and endo connector.

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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2012-08-27** Date: **2021-02-24** Expiry Date: **2023-09-24**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 588902

Issued To:

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

Number	Device name	Intended purpose
Class IIb - Sterile		
GMDN 34917	Silicone 2-way Foley Catheter with Integrated Long-Term balloon	Used for drainage of urine from the bladder for up to 90 days.
GMDN 34917	Silicone 2-Way Foley Balloon Catheter (with/without groove)	Used for drainage of urine from the bladder for up 29 days (with subsequent continuous long-term use).
GMDN 34917	Silicone 3-Way Foley Balloon Catheter	Used for drainage of urine from the bladder for up 29 days (with subsequent continuous long-term use) and to inject water via an irrigation funnel for flushing the bladder.
GMDM 34930	Silicone 3-Way Hematuria Catheter	Used for the drainage of urine from the bladder after prostatectomy and to irrigate the bladder post-surgery for flushing of blood clots/other debris from bladder.
GMDN 34917	Silicone Foley Catheter with Rigid Guide	Used to assist in the percutaneous insertion of catheter and drainage when indicated and in TVT surgery. Used for urethral length measurement.
GMDN 10735	Silicone Nephrostomy Catheter	Used for the drainage of urine from the kidney. It is inserted through the skin into the kidney.
GMDN 34924	Silicone Supra-Pubic Catheter	Used for the drainage of urine from the bladder. It is inserted through a suprapubic incision directly into the bladder.
GMDN 34924	Supra-Pubic Catheter Puncture Set (consisting of catheter, split cannula, clamp & spigot)	Used to gain a percutaneous suprapubic access via the lower abdominal wall, to the urinary bladder for placement of supra-pubic catheter.

First Issued: **2012-08-27** Date: **2021-02-24** Expiry Date: **2023-09-24**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 588902

Issued To:

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

Number	Device name	Intended purpose
GMDN 34924	Supra-Pubic Catheter Exchange Set (catheter, guidewire, clamp & spigot)	Used for the drainage of urine from the bladder. It is inserted through a suprapubic incision directly into the bladder.
GMDN 35404	Silicone Tracheostomy Tube	Placed into a surgical created opening of the trachea to facilitate ventilation to the lungs.
GMDM 14221	Silicone Stomach (Gastric) Tube	Used for nasogastric nutritional supplementation to stomach.
GMDM 35419	Silicone Gastrostomy Catheter	Used for long-term enteral feeding. Introduced via a surgically created opening.
Class IIa - Sterile		
MD 0106	Wound Drainage Trocars	N/A
MD 0106	Silicone Drains, Drain Kits and Drain Sets	
MD 0106	Silicone Closed Wound Vacuum Drain Systems & Drain Bag Systems	
MD 0106	Silicone Endo/Hubless Endo Drains and Kits	
MD 0106	Silicone T, Y & T-Y Drains	
MD 0106	Silicone Penrose Drain Tubes	
MD 0106	Silicone Sump Drain Tube & Foley Sump Drain Tube	
MD 0106	Silicone Thoracic Drain Tubes	
MD 0106	Silicone Vessel ID Loops	

First Issued: **2012-08-27** Date: **2021-02-24** Expiry Date: **2023-09-24**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 588902

Issued To:

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

Number	Device name	Intended purpose
MD 0106	Silicone Surgical Ruler	N/A
MD 0106	Silicone Gastroplasty Calibration Tube	
MD 0101	Silicone Endotracheal Tube	
Class IIa – Non-Sterile		
MD 0106	Single Use Laryngeal Mask Tube	N/A
MD 0101	Single Use Manual Resuscitator Sets containing Single Use Accessories: PVC Resuscitator, Silicone Resuscitator, Sil-Crush Mask, PVC Air-Crush Mask, Silicone Mask, Oxygen Reservoir and Reservoir Valve, Oxygen Tubing, Patient Valve, PEEP Valve & PEEP Valve Diverter	
MD 0106	Reusable Birth-Vac Cup	
Class I - Sterile		
MD 0106	Silicone Closed Wound Vacuum Reservoir	N/A
MD 0106	Collection Bag	
MD 0106	Endo Connector	

First Issued: **2012-08-27** Date: **2021-02-24** Expiry Date: **2023-09-24**

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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:	**2021-02-24**
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**
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	**EU Representative**
Fortune Medical Instrument Corp No. 256, Changchun 2nd Road Jhongli Dist Taoyuan City 320 Taiwan	**Design** **ETO Sterilization** **Final Inspection** **Manufacture** **Regulatory Compliance**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 588902**

Date: **2021-02-24**

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.
25 February 2019	7932553	Traceable to NB 0086.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 588902**

Date: **2021-02-24**

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
24 February 2021	9788667	Amendment to scope to add "non-sterile birth-vac cup" and "non-sterile manual resuscitator sets" Clarification of certificate scope to replace the term "and accessories" with "sets" with full definition of sets provided in supplementary device table Reformatting of certificate scope to separate list of sterile and non-sterile devices Reformatting of certificate scope to list Class Is accessories separately (closed wound vacuum reservoir, collection bag & endo connector) Administrative change to address for EU Representative Administrative addition of supplementary device table Clarification of Class IIa Non-Sterile devices as either reusable or single use in supplementary device table.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
30 November 2021	3483419	Addition of EU Representative, Emergo Europe and removal of EU Representative, PRIM S.A.

Inspiring trust for a more resilient world.

30 November 2021

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

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 588902	93/42/EEC Annex II excluding Section 4	3483419	Addition of EU Representative, Emergo Europe and removal of EU Representative, PRIM S.A.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com
bsigroup.nl

DECLARATION OF CONFORMITY

MANUFACTURER:

FORTUNE MEDICAL INSTRUMENT CORP.

6FL., NO. 29, SEC. 2, JHONGJHENG E. RD., DANSHUEI DIST., NEW TAIPEI CITY 251, TAIWAN

(FACTORY) NO. 256, CHANGCHUN 2ND RD., JHONGLI DIST, TAOYUAN CITY 320, TAIWAN

Single registration number (SRN):N/A

EUROPEAN REPRESENTATIVE:

Emergo Europe

Prinsessegracht 20, 2514 AP The Hague, The Netherlands
Tel: (31) (0) 70 345-8570

Single registration number (SRN): NL-AR-000000116

PRODUCT NAME: Silicone Endotracheal Tube

NO. OF PRODUCT: 1510, 1520, 1525, 1530, 1535, 1540, 1545, 1550, 1555 series

CLASSIFICATION: Class IIa, Rule 5 (According to Annex IX of the MDD)

GMDN CODE: 46967

Basic UDI-DI: 471096193070501HD

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:
MDD 93/42/EEC(INCLUDING 2007/47/EC), EN ISO 13485:2016, ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 11135:2014, EN ISO 11607-1:2020, EN ISO 11607-2:2020, BS EN ISO 14644-1&2:2015, EN ISO 14971:2019, EN ISO 5361:2016

COMMON SPECIFICATION(CS): N/A

NOTIFIED BODY:
BSI Netherlands NB (2797)
Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

CONFORMITY ASSESSMENT ROUTE: **Annex II excluding section 4**

(EC) CERTIFICATE: CE 588902

START OF CE MARKING: October 5, 2018

SIGNATURE: CHEN, MING HONG

FUNCTION: Person responsible for regulatory compliance

PLACE AND DATE OF ISSUE: Taiwan, May 26, 2021

DECLARATION OF CONFORMITY

MANUFACTURER:

FORTUNE MEDICAL INSTRUMENT CORP.
6FL., NO. 29, SEC. 2, JHONGJHENG E. RD., DANSHUEI DIST., NEW TAIPEI CITY 251, TAIWAN
(FACTORY) NO. 256, CHANGCHUN 2ND RD., JHONGLI DIST, TAOYUAN CITY 320, TAIWAN
Single registration number (SRN):N/A

EUROPEAN REPRESENTATIVE:

Emergo Europe
Prinsessegracht 20, 2514 AP The Hague, The Netherlands
Tel: (31) (0) 70 345-8570
Single registration number (SRN): NL-AR-000000116

PRODUCT NAME:	Silicone Thoracic Drain Tube
NO. OF PRODUCT:	2018 series
CLASSIFICATION:	Class IIa, Rule 7 (According to Annex IX of the MDD)
GMDN CODE:	11308
Basic UDI-DI:	471096193040201FV

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:
MDD 93/42/EEC(INCLUDING 2007/47/EC), EN ISO 13485:2016, ISO 10993-1:2018, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-6:2016, EN ISO 10993-10:2013, EN ISO 10993-11:2018, EN ISO 15223-1:2016 , EN ISO 11135:2014, EN ISO 11607-1:2020, EN ISO 11607-2:2020, BS EN ISO 20697:2018, BS EN ISO 14644-1&2:2015, EN ISO 14971:2019

COMMON SPECIFICATION(CS): N/A

NOTIFIED BODY:
BSI Netherlands NB (2797)
Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

CONFORMITY ASSESSMENT ROUTE:	**Annex II excluding section 4**
(EC) CERTIFICATE:	CE 588902
START OF CE MARKING:	December 16, 1998

SIGNATURE: CHEN, MING HONG

FUNCTION: Person responsible for regulatory compliance

PLACE AND DATE OF ISSUE: Taiwan, May 26, 2021