Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin 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 contact@ericon.md,

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 1580 series Laryngeal Mask Tube
- Fortune 2018 series Thoracic Drain Tube
- Fortune Silicone Drainage Tube XX-XXXXXX series
- Fortune Drainage Tube 1910 series
- Fortune Endotracheal Tube 1555 series

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 1580 series Laryngeal Mask Tube
- Fortune 2018 series Thoracic Drain Tube
- Fortune Silicone Drainage Tube XX-XXXXXX series
- Fortune Drainage Tube 1910 series
- Fortune Endotracheal Tube 1555 series

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 **ERICON SRL**, based in 6,Vasile Lupu str. Durlesti. 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

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 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**

...making excellence a habit.™

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:	**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**

...making excellence a habit.™

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.

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 T-Drainage Tube, Silicone Y-Drainage Tube, Silicone T-Y Drainage Tube
NO. OF PRODUCT:	1910, 1920, 1930 series
CLASSIFICATION:	Class IIa, Rule 7 (According to Annex IX of the MDD)
GMDN CODE:	11307
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 7, 1998

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 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:	Laryngeal Mask Tube
NO. OF PRODUCT:	1580 series
CLASSIFICATION:	Class IIa, Rule 5 (According to Annex IX of the MDD)
GMDN CODE:	45035
Basic UDI-DI:	471096193060401GV

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 10993-6:2016, EN ISO 10993-10:2013, EN ISO 10993-11:2018, EN ISO 15223-1:2016, EN 1041:2008, ISO 11712:2009, 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:	June 10, 2008

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 Drainage Tube (non-sterile)
NO. OF PRODUCT:	XX-XXXXXX series
CLASSIFICATION:	Class IIa, Rule 7 (According to Annex IX of the MDD)
GMDN CODE:	14191
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 , 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:	November 6, 1998

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

Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1580 series	Laryngeal Mask Tube	Laryngeal Mask Tube	1580 series	45035
XX-XXXXXX series	Silicone Drainage Tube (non-sterile)	Silicone Drainage Tube (non-sterile)	XX-XXXXXX series	14191
2018 series	Silicone Thoracid Drain Tube	Silicone Thoracid Drain Tube	2018 series	11308
1910 series	Silicone T-Drainage Tube, Silicone Y-Drainage Tube, Silicone T-Y Drainage Tube	Silicone T-Drainage Tube, Silicone Y-Drainage Tube, Silicone T-Y Drainage Tube	1910 series	11307
1555 series	Silicone Endotracheal Tube	Silicone Endotracheal Tube	1555 series	46967