

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

Către Agenția Medicamentului
și 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 și Instrucțiunilor de utilizare în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- Fortune Foley Catheter 1821 series
- Fortune Foley Catheter 1830 series
- Fortune Gastrostomy Catheter 2019-00 series
- Fortune Gastrostomy Catheter 2019-05 series
- Fortune Stomach tube 2020 series
- Fortune Tracheostomy tube 1565 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

DECLARAȚIE PE PROPRIE RĂSPUNDERE

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

declar pe proprie răspundere, cunoscând prevederile art. **352¹**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

- Fortune Foley Catheter 1821 series
- Fortune Foley Catheter 1830 series
- Fortune Gastrostomy Catheter 2019-00 series
- Fortune Gastrostomy Catheter 2019-05 series
- Fortune Stomach tube 2020 series
- Fortune Tracheostomy tube 1565 series

Sunt autentice și corespund realității.

Gheorghe Bunic

Semnătura _____

Data _____



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**

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 588902****Issued To:**

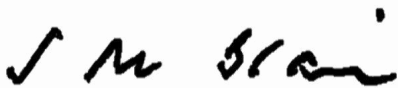
**Fortune Medical Instrument Corp
6F., No. 29, Sec. 2, Jhongjheng E.Rd.,
Danshuei Dist,
New Taipei City
251
Taiwan**

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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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.

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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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.

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 Foley Catheter

NO. OF PRODUCT: 1821,1822,1823,1824,1827,1856,1830,4822,4856,4833 Series

CLASSIFICATION: Class IIb, Rule5 (According to Annex IX of the MDD)

GMDN CODE: 34917

Basic UDI-DI: 471096193020101F2

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC AND REGULATION (EU) 2017/745 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 10993-11:2018, EN ISO 10993-3:2014, EN ISO 15223-1:2016, BS EN ISO 11135: 2014, ISO 11607-1: 2018, EN ISO 11607-2: 2017, EN ISO 14971: 2019, EN 1041: 2008, BS EN ISO 20696: 2018,ASTM F623: 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: Nov. 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 Gastrostomy Catheter
Silicone Gastrostomy Catheter with ENFit Connector

NO. OF PRODUCT: 2019-00xx series
2019-05xx series

CLASSIFICATION: Class IIb, Rule 8 (According to Annex IX of the MDD)

GMDN CODE: 35419

Basic UDI-DI: 471096193100702FR

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 10993-11:2018, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 11135:2014, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 20695:2020, EN ISO 80369-3:2016, 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: Jan. 20, 2001

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 Stomach Tube,
Silicone Gastric Tube, Detachable Type
Silicone nasogastric Tube with ENFit connector

NO. OF PRODUCT: 2020-00xx series
2020-55xx/60xx/65xx/70xx/75xx series
2020-05xx series

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

GMDN CODE: 14221

Basic UDI-DI: 471096193100701FP

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 10993-10:2013, EN ISO 10993-11:2018, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 11135:2014, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 20695:2020, 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, MENG 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 Tracheostomy Tube

NO. OF PRODUCT: 1560, 1561, 1565 series

CLASSIFICATION: Class IIb, Rule 8 (According to Annex IX of the MDD)

GMDN CODE: 35404

Basic UDI-DI: 471096193080501HQ

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 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 5366:2016

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: January 16, 2006

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*
1821 series	Silicone Foley Catheter	Silicone Foley Catheter	1821 series	34917
1830 series	Silicone Foley Catheter	Silicone Foley Catheter	1830 series	34917
2019-00xx series	Silicone Gastrostomy Catheter Silicone Gastrostomy Catheter with ENFit Connector	Silicone Gastrostomy Catheter Silicone Gastrostomy Catheter with ENFit Connector	2019-00xx series	35419
2019-05xx series	Silicone Gastrostomy Catheter Silicone Gastrostomy Catheter with ENFit Connector	Silicone Gastrostomy Catheter Silicone Gastrostomy Catheter with ENFit Connector	2019-05xx series	35419
2020-00xx series	Silicone Stomach Tube, Silicone Gastric Tube, Detachable Type Silicone nasogastric Tube with ENFit connector	Silicone Stomach Tube, Silicone Gastric Tube, Detachable Type Silicone nasogastric Tube with ENFit connector	2020-00xx series	14221
2020-55xx series	Silicone Stomach Tube, Silicone Gastric Tube, Detachable Type Silicone nasogastric Tube with ENFit connector	Silicone Stomach Tube, Silicone Gastric Tube, Detachable Type Silicone nasogastric Tube with ENFit connector	2020-55xx series	14221
2020-05xx series	Silicone Stomach Tube, Silicone Gastric Tube, Detachable Type Silicone nasogastric Tube with ENFit connector	Silicone Stomach Tube, Silicone Gastric Tube, Detachable Type Silicone nasogastric Tube with ENFit connector	2020-05xx series	14221
1565 series	Silicone Tracheostomy Tube	Silicone Tracheostomy Tube	1565 series	35404