

### Formularul ofertei (F3.1)

Data depunerii ofertei: **"24" iulie 2020**

Procedura de achiziție Nr.: **ocds-b3wdp1-MD-1595401252443/21026415**

Denumirea obiectului de achiziții: **"Bahile, bonete, cearșaf medical"**

Către: **IMSP Institutul de Medicina Urgentă**

**"Endo-Chirurgie" SRL** declară că:

- a) Au fost examinate și nu există rezervări față de documentele de atribuire, inclusiv modificările nr. nu se aplică.
- b) **"Endo-Chirurgie" SRL** se angajează să furnizeze în conformitate cu documentele de atribuire și condițiile stipulate în specificațiile tehnice și preț, următoarele bunuri: **"Bahile, bonete, cearșaf medical"**.
- c) Suma totală a ofertei fără TVA constituie: **45 725.00 (patruzeci și cinci mii șapte sute douăzeci și cinci lei, 00 bani) lei MD.**
- d) Suma totală a ofertei cu TVA constituie: **54 870.00 (cincizeci și patru mii opt sute șaptezeci lei, 00 bani) lei MD.**
- e) Prezenta ofertă va rămâne valabilă pentru perioada de timp specificată în **FDA3.8.**, începînd cu data-limită pentru depunerea ofertei, în conformitate cu **FDA4.2.**, va rămîne obligatorie și va putea fi acceptată în orice moment pînă la expirarea acestei perioade;
- f) În cazul acceptării prezentei oferte, **"Endo-Chirurgie" SRL** se angajează să obțină o Garanție de bună execuție în conformitate cu **FDA6**, pentru executarea corespunzătoare a contractului de achiziție publică.
- g) Nu sîntem în nici un conflict de interese, în conformitate cu art. 74 din Legea nr. 131 din 03.07.2015 privind achizițiile publice.
- h) Compania semnatară, afiliații sau sucursalele sale, inclusiv fiecare partener sau subcontractor ce fac parte din contract, nu au fost declarate neeligibile în baza prevederilor legislației în vigoare sau a regulamentelor cu incidență în domeniul achizițiilor publice.

Semnat: \_\_\_\_\_

Nume: **Victor GHEREG**

În calitate de: **Director**

Ofertantul: **"Endo-Chirurgie" SRL**

Adresa poștală: **Republica Moldova, mun. Chișinău, str. Meșterul Manole, nr. 9.**

Data: **"24" iulie 2020**



"Endo-Chirurgie" S.R.L.

Codul fiscal: 1009600033242

Adresa poștală: mun.Chișinău, str. Meșterul Manole, nr. 9.

Telefon/Fax: (022) 23-21-33, (022) 66-72-86



Nr. de ieșire: 40/07 din 24.07.2020

Către: IMSP Institutul de Medicina Urgență,

Numărul unic al procedurii de achiziție: ocds-b3wdp1-MD-1595401252443/21026415,

"Bahile, bonete, cearșaf medical.

## DECLARAȚIE

Prin prezenta, SRL "Endo-Chirurgie" declară următoarele:

1. Dispune în stoc de 295 cutii de bonete medicale, ceea ce reprezintă 29 500 buc, așa cum a fost specificat în formularul F4.2.
2. În cazul în care oferta noastră va fi declarată drept câștigătoare, pentru cantitatea specificată la pct. 1 din prezenta declarație, suntem în stare să livrăm bunurile în decurs de 24 de ore.

Cu respect,

Director



Victor GHEREG

Ex. P. Dubalari

Tel./fax.: 022-23-21-33



## I.P. "AGENȚIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de drept

### EXTRAS

din Registrul de stat al persoanelor juridice

nr. 26597 din 15.05.2020

Denumirea completă: **Societatea cu Răspundere Limitată «ENDO-CHIRURGIE».**

Denumirea prescurtată: **«ENDO-CHIRURGIE» S.R.L.**

Forma juridică de organizare: **Societate cu Răspundere Limitată.**

Numărul de identificare de stat și codul fiscal: **1009600033242.**

Data înregistrării de stat: **24.09.2009.**

Sediul: **MD-2021, str. Drumul Viilor, 30/2, ap.(of.) 54, mun. Chișinău, Republica Moldova.**

Modul de constituire: **nou creată.**

Obiectul principal de activitate:

- 1 Acordarea asistenței medicale de către instituțiile medico-sanitare private;**
- 2 Activitatea farmaceutică;**
- 3 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 4 Comerțul cu amănuntul al articolelor medicale și ortopedice;**
- 5 Comerțul cu amănuntul al produselor cosmetice și de parfumerie, articolelor de toaletă;**
- 6 Alte activități de asistență medicală;**
- 7 Activități de întreținere corporală;**
- 8 Activități de consultare pentru afaceri și management;**
- 9 Activități de cercetare a pieței și de sondaj al opiniei publice;**
- 10 Importul și (sau) fabricarea, depozitarea, comercializarea angro a substanțelor și materialelor chimice, toxice, articolelor și produselor chimice de menaj;**
- 11 Importul și (sau) depozitarea, comercializarea produselor de uz fitosanitar și (sau) a fertilizanților.**

Capitalul social: **1132300 lei.**

Administrator: **GEREG VICTOR, IDNP 2003001030201,**

Asociați:

- 1. GEREG DAN , IDNP 2005001063818**  
**cota 1132300.00 lei, ce constituie 100 %.**

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 15.05.2020.

Specialist coordonator  
tel. 022-207-840





REPUBLICA



MOLDOVA

# CERTIFICAT DE ÎNREGISTRARE

Societatea cu Răspundere Limitată

"ENDO-CHIRURGIE"

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal

1009600033242

Data înregistrării

24.09.2009

Data eliberării

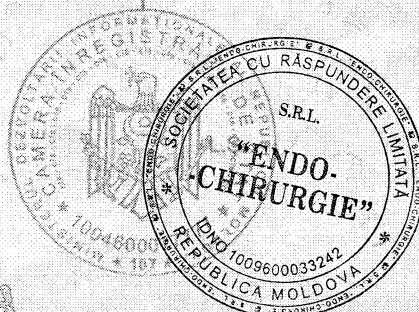
24.09.2009

Jimbei Mihai, registrator

Funcția, numele, prenumele persoanei  
care a eliberat certificatul

  
semnătura

MD 0097512







Nr. 12/19-2375

Data 25.02.16

## CERTIFICAT PRIVIND EXISTENTA CONTURILOR CURENTE

Prin prezentul, **BC „Mobiasbancă – Groupe Societe Generale” S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **ENDO-CHIRURGIE SRL** cod fiscal (IDNO) 1009600033242, detine următoarele conturi curente la BC Mobiasbanca-Groupe Societe Generale SA, Filiala. 09 Centru :

1. **MDL - MD53MO2224ASV56624407100**
2. **USD - MD88MO2224ASV56624677100**
3. **EUR - MD80MO2224ASV56624837100**

Certificatul este emis in baza cererii întreprinderii **ENDO-CHIRURGIE SRL**

**Diana Pranitchi L.Ş.**  
Numele, Prenumele si Semnătura  
Director filiala „09 Centru”

Executor: V.Marcov  
Tel: 0 22 812 562

Filiala Nr. 9 „Centru”  
Bd. Ștefan cel Mare și Sfânt 81a  
MD-2012, Chișinău, Moldova  
Cod MOBBMD22  
Cont de corespondență 35213892  
la Centrul de Decontări al BNM

Tel. +373 22 81 21 10  
Fax. +373 22 27 92 67  
www.mobiasbanca.md

Contacte  
+373 22 25 64 56

BC „Mobiasbancă – Groupe Societe Generale” SA  
Capital Social: 100 000 000 MDL  
Număr de înregistrare de stat : 1002600006089  
Sediul Central:  
bd. Ștefan cel Mare și Sfânt 81a  
MD-2012, Chișinău, Moldova

GRUPE SOCIETE GENERALE

# EC Certificate - Full Quality Assurance System

## Certificate History

Certificate No: **CE 621870**  
 Date: **02 March 2016**  
 Issued To: **Halyard Health, Inc.**  
**5405 Windward Parkway**  
**Alpharetta**  
**Georgia**  
**30004**  
**USA**

Date	Reference Number	Action
23 March 2015	8255587	First issue, mirror certificate of CE 556100.
30 November 2015	8411341	Addition of significant subcontractor Sterigenics US, LLC, 3125 Wichita Court, Fort Worth, Texas 76140, USA for Gamma Sterilization. Subcontractor name change from 'MMC Sterilization Services Group, Inc.' to 'iuvo BioScience - Erie, LLC'. Correction of subcontractor address for 'Unomedical Sdn. Bhd.,' to include 'Kedah'. Correction of subcontractor address for 'Avent R.L. de C.V.' (Magdalena) and 'Avent R.L. de C.V.' (Circuito Industrial No, 40, Nogales) to include 'Sonora'. Correction of subcontractor address for 'Trident Manufacturing Inc.' from '14N002 Prairie Grove, Illinois' to '14N002 Prairie Street, Illinois 60140'.
02 March 2016	8472511	Addition of 'Sterile Anesthesia Conduction Needles and Kits' to the product list. Certificate renewal.



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Page 1 of 1

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 621870**  
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**5405 Windward Parkway**  
**Alpharetta**  
**Georgia**  
**30004**  
**USA**

Subcontractor:	Service(s) supplied
Avent Inc - ATW 6620 S. Memorial Place, Suite 100 Tucson Arizona 85756 USA	Manufacture
Avent R.L. de C.V. Carretera Internacional Salida Norte 1053 Magdalena Sonora CP 84160 Mexico	Manufacture
Avent S de R.L. de C.V. Circuito Industrial No. 40 Colonia Obrera Nogales Sonora CP 84048 Mexico	Manufacture



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# EC Certificate - Full Quality Assurance System

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

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**Alpharetta**  
**Georgia**  
**30004**  
**USA**

### Subcontractor:

### Service(s) supplied

Avent S. de R.L. de C.V.  
 Avenida del Castillo #17-B  
 Nogales  
 CP 84094  
 Mexico

**Manufacture**

Baylis Medical Company Inc.  
 5959 Trans-Canada Highway  
 Montreal  
 Québec H4T 1A1  
 Canada

**Manufacture**

Centurion Sterilization Services  
 A Division of Centurion Medical  
 Products Corporation  
 3173 East 43rd Street  
 Yuma  
 Arizona 85365  
 USA

**ETO Sterilization**



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**Alpharetta**  
**Georgia**  
**30004**  
**USA**

### Subcontractor:

### Service(s) supplied

Centurion Sterilization Services  
 A Division of Tri-State Hospital Supply  
 301 Catrell Drive  
 Howell  
 Michigan 48843  
 USA

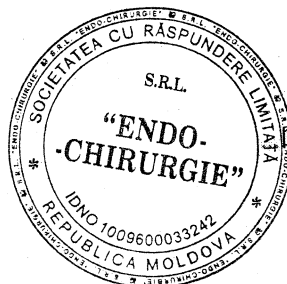
**ETO Sterilization**

Halyard - Irvine  
 43 Discovery, Suite 100  
 Irvine  
 California 92618  
 USA

**Administration & Complaints**

Halyard Belgium BVBA  
 Leonardo Da Vincilaan 1  
 1930 Zaventem  
 Belgium

**EU Representative**



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**Alpharetta**  
**Georgia**  
**30004**  
**USA**

### Subcontractor:

### Service(s) supplied

iuvo BioScience - Erie, LLC  
 2205 East 33rd Street  
 Erie  
 Pennsylvania 16510  
 USA

**ETO Sterilization**

Martech Medical Products  
 1500 Delp Drive  
 Harleysville  
 Pennsylvania 19438  
 USA

**Manufacture**

Sterigenics US, LLC,  
 3125 Wichita Court  
 Fort Worth, 76140  
 Texas  
 USA

**Gamma Sterilization**



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# EC Certificate - Full Quality Assurance System

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

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**Alpharetta**  
**Georgia**  
**30004**  
**USA**

### Subcontractor:

### Service(s) supplied

Sterigenics US, LLC  
 344 Bonnie Circle  
 Corona  
 California 92880  
 USA

**Gamma Sterilization**

STERIS Isomedix Services Inc.  
 9120 South 150 East  
 Sandy  
 Utah 84070  
 USA

**Gamma Sterilization**

STERIS Isomedix Services, Inc.  
 1435 Isomedix Place  
 El Paso  
 Texas 79936  
 USA

**ETO Sterilization**  
**Gamma Sterilization**



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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

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**Alpharetta**  
**Georgia**  
**30004**  
**USA**

### Subcontractor:

### Service(s) supplied

STERIS Isomedix Services  
 1000 South Sarah Place  
 Ontario  
 California  
 91761  
 USA

**Gamma Sterilization**

STERIS Isomedix Services  
 43425 Business Park Drive  
 Temecula  
 California  
 92590  
 USA

**ETO Sterilization**

Synergy Sterilisation Kulim  
 (M) Sdn Bhd  
 Lot 71, Kulim Industrial Estate  
 09000 Kulim  
 Kedah  
 Malaysia

**ETO Sterilization**



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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 621870**  
 Date: **02 March 2016**  
 Issued To: **Halyard Health, Inc.**  
**5405 Windward Parkway**  
**Alpharetta**  
**Georgia**  
**30004**  
**USA**

### Subcontractor:

### Service(s) supplied

Trident Manufacturing Inc.  
 14N002 Prairie Street  
 Pingree Grove  
 Illinois 60140  
 USA

**Manufacture**

Unomedical Snd. Bhd.,  
 Bakar Arang Industrial Estate  
 08000 Sungai Petani  
 Kedah  
 Malaysia

**Manufacture**



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# EC Certificate - Full Quality Assurance System

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

**No.****CE 621870****Issued To:**

**Halyard Health, Inc.  
5405 Windward Parkway  
Alpharetta  
Georgia  
30004  
USA**

**In respect of:**

**The design, development and manufacture of Enteral Feeding Devices, Access Devices, Closed Tracheal and Oral Suction Systems, Non-Active Endoscopy Devices and Accessories, sterile Non-Active Respiratory Devices, Digestive Tract Devices, Endotracheal Tubes, Gastrointestinal Anchor Sets, Cannulas/Introducers for use in RF Pain Management Systems and sterile Anesthesia Conduction Needles and Kits**

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):



Frank Lee, EMEA Compliance & Risk Director

**First Issued: 23 March 2015****Date: 02 March 2016****Expiry Date: 13 February 2021**

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Page 1 of 2

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

## Supplementary Information to CE 621870

Issued To:

**Halyard Health, Inc.**  
**5405 Windward Parkway**  
**Alpharetta**  
**Georgia**  
**30004**  
**USA**

### This certificate covers the following products:

Enteral Feeding Devices Gamma Sterilized  
Enteral Feeding Devices EtO Sterilized i.e. 12F MIC-Key, PEG  
Enteral Feeding Accessories i.e. Extension Sets, PEG Accessories, Dilation Systems  
Introducer Kits  
Closed Suction System and Accessories  
Oral Care System and Accessories  
MAC Cath  
Polypectomy Snare  
Thermal Option Biopsy Forceps  
Injection Needle Catheters  
Paracentesis Tray, Kit and Needles  
BAL Cath  
Retrieval Devices i.e. Baskets, Graspers  
Cuffed Endotracheal Tubes  
Gastrointestinal Anchor Sets  
Cannulas/Introducers for use in RF Pain Management Systems  
Sterile Anesthesia Conduction Needles and Kits

First Issued: **23 March 2015**Date: **02 March 2016**Expiry Date: **13 February 2021**

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Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained in accordance with the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products not 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.



By Royal Charter

# EC Certificate - Production Quality Assurance

## Certificate History

Certificate No: **CE 698961**  
Date: **2019-02-25**  
Issued To: **O & M Halyard, Inc.**  
**9120 Lockwood Blvd**  
**Mechanicsville**  
**Virginia**  
**23116**  
**USA**

Date	Reference Number	Action
18 February 2019	9643055	First Issue.
Current	9643448	Traceable to NB 0086.



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Page 1 of 1

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780  
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.  
A member of BSI Group of Companies.



# 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 698961**  
 Date: **2019-02-25**  
 Issued To: **O & M Halyard, Inc.**  
**9120 Lockwood Blvd**  
**Mechanicsville**  
**Virginia**  
**23116**  
**USA**

Subcontractor:	Service(s) supplied
Arc Royal Virginia Road Kells Co Meath Ireland	EU Representative
GRI Medical & Electronic Technology Co., Ltd 1805 Honggao Road Jiaxing Zhejiang 314031 China	ETO Sterilization Manufacture
Isomedix Operations, Inc. 1441 Don Haskins Drive El Paso Texas 79936 USA	ETO Sterilization



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# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

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**9120 Lockwood Blvd**  
**Mechanicsville**  
**Virginia**  
**23116**  
**USA**

Subcontractor:	Service(s) supplied
La Ada de Acuna S. De. R.L. De C.V. Av. Hidalgo No. 6 Esq., Blvd. Luis Donaldo Colosio Col. Educativa, Nogales Sonora 84093 Mexico	Manufacture
Lianyungang Aiyeh Non-Woven Products Co., Ltd No. 9 YunYang Rd. Huangjiuni Export Processing Zone Lianyungang, Jiangsu 222047 China	Manufacture
Master & Frank (Pinghu) Ent. Co., Ltd. No. 2000, Xingping II Rd. Pinghu Economic Development Zone Zhejiang P.R. China	Manufacture



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# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

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**9120 Lockwood Blvd**  
**Mechanicsville**  
**Virginia**  
**23116**  
**USA**

Subcontractor:	Service(s) supplied
O&M Halyard Honduras S.A. de C.V. Carretera Tegucigalpa Villanueva Cortes Honduras	Manufacture
O&M Halyard, Inc. 5405 Windward PKWY Alpharetta Georgia 3004 USA	Regulatory Compliance
SAFESKIN MEDICAL & SCIENTIFIC (THAILAND), LTD. 200 moo 8 Kanchanavanich Road Tambol Prik, Amphur Sadao Songkhla, 90120 Thailand	Manufacture



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# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

## List of Significant Subcontractors

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 Issued To: **O & M Halyard, Inc.**  
**9120 Lockwood Blvd**  
**Mechanicsville**  
**Virginia**  
**23116**  
**USA**

### Subcontractor:

### Service(s) supplied

Sterigenics S. de R. L. de C. V.  
 James Watt No. 22  
 Parque Industrial Cuamatla  
 Cuautitlan Izcalli  
 Estado de México  
 C.P. 54730  
 Mexico

**ETO Sterilization**

Sterigenics US, LLC  
 10821 Withers Cove Park Drive  
 Charlotte  
 North Carolina  
 28278  
 USA

**Gamma Irradiation**

Sterigenics US, LLC  
 1302 Avenue T  
 Grand Prairie  
 Texas  
 75050  
 USA

**ETO Sterilization**



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# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

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 Issued To: **O & M Halyard, Inc.**  
**9120 Lockwood Blvd**  
**Mechanicsville**  
**Virginia**  
**23116**  
**USA**

Subcontractor:	Service(s) supplied
Sterigenics US, LLC 687 S. Wanamaker Avenue Ontario California 91761 USA	ETO Sterilization
Sterigenics US, LLC 2971 Olympic Industrial Drive SE Suite 116 Atlanta Georgia 30339 USA	ETO Sterilization
Sterigenics US, LLC 2400 Airport Road Santa Teresa New Mexico 88008 USA	ETO Sterilization



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**Mechanicsville**  
**Virginia**  
**23116**  
**USA**

### Subcontractor:

### Service(s) supplied

Synergy Health (Thailand) Ltd  
 700/465 Amata Nakorn Industrial Estate  
 Moo 7, Tambol Donhuaroh  
 Amphur Muang  
 Chonburi 20000  
 Thailand

**Gamma Sterilization**

Synergy Sterilisation (M) Sdn Bhd  
 Plot 203  
 Kuala Ketil Industrial Estate  
 Kuala Ketil  
 Kedah  
 09300  
 Malaysia

**Gamma Sterilization**



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# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

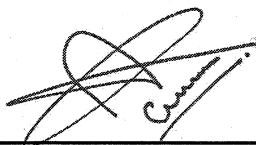
**No.****CE 698961****Issued To:****O & M Halyard, Inc.  
9120 Lockwood Blvd  
Mechanicsville  
Virginia  
23116  
USA**

In respect of:

**The manufacture of Surgical Drapes.****Those aspects of Annex V related to securing and maintaining sterility in the manufacture of sterile surgical gowns, surgical drapes, surgical packs and examination gloves**

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 2797):



Albert Roossien, Regulatory Lead

First Issued: **2019-02-18**Date: **2019-02-25** **ENDO-CHIRURGIE** Expiry Date: **2024-02-17**

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Page 1 of 2

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.

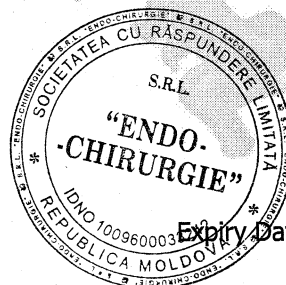
# EC Certificate - Production Quality Assurance

**Supplementary Information to CE 698961**

Issued To:

**O & M Halyard, Inc.  
9120 Lockwood Blvd  
Mechanicsville  
Virginia  
23116  
USA**

Number	Device Name	Intended Purpose per IFU
<b>Class IIa</b>		
MD 0101	Transurethral Resection (T.U.R.) Drapes & Packs	N/A
<b>Class Is</b>		
MDS7006	Surgical Gowns	N/A
MDS7006	Surgical Drapes	N/A
MDS7006	Surgical Packs	N/A
MDS7006	Examination Gloves	N/A



First Issued: **2019-02-18**

Date: **2019-02-25**

Expiry Date: **2024-02-17**

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Page 2 of 2

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780  
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.  
A member of BSI Group of Companies.



By Royal Charter

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

O & M Halyard, Inc.  
9120 Lockwood Blvd  
Mechanicsville  
Virginia  
23116  
USA

Holds Certificate No:

**FM 697013**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design and development, manufacture and distribution of surgical gowns, protective garments, face masks, surgical drapes, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Packs, orthopedic packs, sterile and non-sterile examination gloves, Temperature management systems for the areas of general surgery and general medical use and sterilization wrap and non-woven materials for medical devices.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2014-12-09

Latest Revision Date: 2020-01-08

Effective Date: 2020-01-09

Expiry Date: 2023-01-08

Page: 1 of 3



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This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.

Certificate No: **FM 697013**

Location

Registered Activities

O & M Halyard, Inc.  
9120 Lockwood Blvd  
Mechanicsville  
Virginia  
23116  
USA

Headquarter management activities.

O & M Halyard, Inc.  
5405 Windward Parkway  
Alpharetta  
Georgia  
30004  
USA

The design and development of surgical gowns, protective garments, face masks, surgical drapes, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Packs, orthopedic packs, sterile and non-sterile examination gloves, Temperature management systems for the areas of general surgery and general medical use and sterilization wrap and non-woven materials for medical devices.

Halyard North Carolina, LLC  
389 Clyde Fitzgerald Rd.  
Linwood  
North Carolina  
27299  
USA

The manufacture of nonwoven materials for medical devices, Sterilization wrap, and infection control products including disposable gowns and linens.

La Ada de Acuna  
14 Finegan Road  
Del Rio  
Texas  
78840  
USA

Receiving and Incoming Inspection, Warehouse and Distribution.

O&M Halyard Honduras S.A. de C.V.  
Carretera Tegucigalpa Villanueva  
Cortes  
Honduras

The manufacture and distribution of disposable sterile and non-sterile surgical gowns.

La Ada de Acuna  
Avenida Hidalgo #16  
Parque Industrial San Carlos  
Nogales  
Sonora  
84092  
Mexico

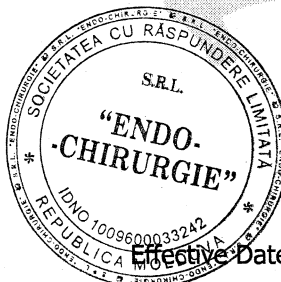
Receiving and incoming inspection. Manufacturer/Conversion of nonwoven materials.

Original Registration Date: 2014-12-09

Latest Revision Date: 2020-01-08

Effective Date: 2020-01-09

Expiry Date: 2023-01-08





Certificate No: **FM 697013**

Location

Registered Activities

La Ada de Acuna  
Kim. 4.5 Carreterra Presa La Amistad  
Ciudad De Acuna  
Coahuila  
26220  
Mexico

The manufacture of non-sterile face masks (surgical isolation, industrial and respirator), non-surgical gowns, cold therapy products, and sterilization wrap.

La Ada de Acuna S.De. R.L. De C.V  
AV. Hidalgo #6 Esq., Blvd.,  
Luis Donaldo Colosio, Col. Educativa  
Nogales Sonora  
84093  
Mexico

The manufacture of disposable products including sterile and non sterile surgical packs, gowns and components. The manufacture of temperature management systems for areas of general surgery.

Safeskin Medical & Scientific  
(Thailand) Ltd.  
200 Moo 8, Kanchanavanich Road,  
Tambol Prik, Amphur Sadao,  
Songkhla  
90120  
Thailand

The design and development, production and distribution of industrial gloves, sterile and non-sterile examination gloves.

Original Registration Date: 2014-12-09  
Latest Revision Date: 2020-01-08



Effective Date: 2020-01-09  
Expiry Date: 2023-01-08

Page: 3 of 3

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