Formularul informativ despre ofertant

1. Denumirea/numele: **”Endo-Chirurgie” SRL**

2. Codul fiscal (IDNO): **1009600033242**, Cod TVA: 0207790

3. Adresa juridică: **mun. Chişinău, str. Drumul Viilor, nr. 30/2, ap.54**.

3.1. **Adresa postală**: **mun.Chişinău, str. Mesterul Manole, nr. 9**.

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

E-mail: info@akson.md

5. Certificatul de înregistrare: **MD 0097512 din 24.09.2009, eliberta de Camera Înregistrării de Stat**.

6. Obiectul de activitate, pe domenii: *1. Acordarea asistenţei medicale de către instituţiile medico-sanitare private. 2. Activitatea farmaceutică. 3. Importul, fabricarea, comercializarea, asistenţa tehnică şi (sau) reparaţia dispozitivelor medicale şi (sau) a opticii. 4. Comerţul cu amănuntul al articolelor medicale. 5. Comerţul cu amănuntul al produselor cosmetice şi de parfumerie, articolelor de toaletă. 6. Alte activităţi de asistenţă medicală. 7. Activităţi de întreţinere corporală. 8. Activităţi de consultare pentru afaceri şi management. 9. Activităţi de cercetare a pieţei şi de sondaj al opiniei publice. 10. Importul şi (sau) fabricarea, depozitarea, comercializarea angro a substanţelor şi materialelor chimice, toxice, articolelor şi produselor chimice de menaj. 11. Importu şi (sau) depozitarea, comercializarea produselor de uz fitosanitar şi (sau) a fertilizanţilor*.

7. Autorizaţie (certificat): **Autorizaţie sanitară de funcţionare nr. 007834/2020/1519 din data de 14.12.2020, eliberată de Agenția Națională pentru Sănătate Publică, Ministerul Sănătății, Muncii și Protecției Sociale al Republicii Moldova, depozitare comerț**.

8. Date bancare: **Cod IBAN**: MD53MO2224ASV56624407100, **Banca**: BC „Mobiasbanca-OTP Group” SA, **Codul băncii**: MOBBMD22.

9. Principala piaţă de afaceri: **Republica Moldova**.

Digitally signed by Dubalari Pavel
Date: 2021.04.13 18:27:18 EEST
Reason: MoldSign Signature
Location: Moldova

Semnat: _____

Denumirea firmei: **”Endo-Chirurgie” SRL**

Nume: **DUBALARI Pavel**

Funcţia în cadrul firmei: **Specialist achiziţii publice, Jurisconsult**

Data completării: **“13” aprilie 2021**

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

L.Ș.

CAMERA ÎNREGISTRĂRII DE STAT ★ 1004600077777 ★ 167 ★ MINISTERUL DEZVOLTĂRII INFORMAȚIONALE AL REPUBLICII MOLDOVA

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. **450896** data **25.09.2020**

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 şi codul fiscal (IDNO): **1009600033242**
Data înregistrării de stat: **24.09.2009**
Sediul: **MD-2021, str. Drumul Viilor, 30/2, ap. 54, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1. Acordarea asistenţei medicale de către instituţiile medico-sanitare private
2. Activitatea farmaceutică
3. Importul, fabricarea, comercializarea, asistenţa tehnică şi (sau) reparaţia dispozitivelor medicale şi (sau) a opticii
4. Comerţul cu amănuntul al articolelor medicale şi ortopedice
5. Comerţul cu amănuntul al produselor cosmetice şi de parfumerie, articolelor de toaletă
6. Alte activităţi de asistenţă medicală
7. Activităţi de întreţinere corporală
8. Activităţi de consultare pentru afaceri şi management
9. Activităţi de cercetare a pieţei şi de sondaj al opiniei publice
10. Importul şi (sau) fabricarea, depozitarea, comercializarea angro a substanţelor şi materialelor chimice, toxice, articolelor şi produselor chimice de menaj
11. Importul şi (sau) depozitarea, comercializarea produselor de uz fitosanitar şi (sau) a fertilizanţilor

Capitalul social: **1132300** lei,

Administrator: **GHEREG VICTOR, IDNP 2003001030201.**

Asociaţii:
1. GHEREG VICTOR, IDNP 2003001030201, cota 1132300 lei, ce constituie 100%
Beneficiar efectiv: GHEREG VICTOR, IDNP 2003001030201.

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: **25.09.2020**.

Registrator **Ciobănică Irina**

INSTITUŢIA PUBLICĂ AGENŢIA SERVICII PUBLICE IDNO 1002600024700 REPUBLICA MOLDOVA CHIŞINĂU 154

EB 0323190

MOBIAS BANCA

Nr. 14/09-2315

Data: 25.02.14

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.Morcov
Tel:0 22 812 562

Filiala Nr. 9 „Centru"
Bd. Ştefan cel Mare şi Sfânt 81a
MD-2012, Chişinău, Moldova
Cod MOBBMD22
Cont de corespondenţă 35213892
la Centrul de Decontări al BNM

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

Contacteli
+373 22 25 64 56

BC „Mobiasbancă – Groupe Société Générale" SA
Capital Social: 100 000 000 MDL
Număr de înregistrare de stat - 1002600006089
Sediul Central:
bd. Ştefan cel Mare şi Sfânt 81a
MD-2012, Chişinău, Moldova

GROUPE SOCIETE GENERALE

Anexa nr.7.2 la Instrucțiunea
aprobată prin ordinul IFPS
nr. 400 din 14 martie 2014

CC 04 AE

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr. / № A2105492 din / от 07.04.2021

1. Destinația / Назначение

AGENȚIA ACHIZIȚII PUBLICE

2. Date despre contribuabil / Информация о налогоплательщике

Denumirea / Наименование	**Codul fiscal / Numărul de identificare** / Фискальный код / Идентификационный номер
ENDO-CHIRURGIE S.R.L.	1009600033242
Adresa sediului de bază (strada, numărul) / Адрес основного месторасположения (улица, номер)	**Codul - Denumirea localității** / Код - Наименование населенного пункта
Drumul Viilor nr.30 bl.2 of.54	0130-SEC.CENTRU

3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat / Подтверждение отсутствия или наличия недоимки согласно данных Информационной автоматизированной системы

La data emiterii prezentului certificat restanța față de bugetul public național constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет: **0,00** lei/лей.

4. Valabil pînă la / Действителен до 22.04.2021

5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы

Șef DDF Centru — **Funcția** Должность

Semnătura Подпись

Albina IȘCOVA — **Numele și prenumele** Фамилия и имя

L.Ș. М.П.

Executor: Gavajuc V. — **Numele și prenumele** Фамилия, имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului"// 07.04.2021 ora 11:30:15
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (80,85)

By Royal Charter

EC Certificate - Production Quality Assurance

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

No. **CE 540596**

Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

In respect of:

Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of non-active respiratory, non-active gynaecological, non-active regional anaesthesia, non-active surgical and non-active urology devices.
Those aspects of manufacturing relating to obtaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Devices Directive.
The manufacture of non-active and active surgical devices for adult and paediatric intraosseous infusion, bone marrow aspiration, bone marrow biopsy, bone lesion biopsy and non-active sterile urology catheters.

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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2009-01-13** Date: **2020-06-09** Expiry Date: **2024-05-26**

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EC Certificate - Production Quality Assurance

Supplementary Information to CE 540596

Issued To:

Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0102	Sterile Intraosseous Vascular Access System	--
MD 1104	Non-sterile Intraosseous Vascular Access System	
MD 0102	Sterile Powered Bone Access	--
MD 1104	Non-sterile Powered Bone Access	
MD 0102	Sterile Sternal Intraosseous Device	--
MD 0101	Sterile Silicone Foley Catheter	--

First Issued: **2009-01-13** Date: **2020-06-09** Expiry Date: **2024-05-26**

EC Certificate - Production Quality Assurance

Supplementary Information to CE 540596

Issued To:

Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Number	Device Name	Intended purpose per IFU
Class Is		
MD 0301	Intraosseous Vascular Access System Stabilizer	--
MD 0102	Powered bone access connector	--
MD 0101	Tracheostomy Tube Accessories	--
MD 0102	Tuohy Borst Adaptor	--
MD 0102	Syringe	--
MD 0101	Urology Dilator	--
MD 0101	Guedel Airway	--
MD 0101	Intrauterine Catheter Set	--
MD 0101	Sterile Container	--
MD 0101	Neckband	--
Sterility aspects only		
---	Procedure Packs under article 12	---

First Issued: **2009-01-13** Date: **2020-06-09** Expiry Date: **2024-05-26**

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By Royal Charter

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 540596**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
ArcRoyal Virginia Road Kells, Co. Meath Ireland	**Manufacture**
Arriol International Corporation Carretera San Isidro KM 17 Zona Franca San Isidro Santo Domingo Este Dominican Republic	**ETO Sterilization** **Manufacture**
Arrow International CR, a.s. Jamska 2359/47 Zdar Nad Sazavou 59101 Czech Republic	**Manufacture**
BBF Sterilisationsservice GmbH Willy-Rüsch-Straße 10/1 71394 Kernen Germany	**Radiation (Gamma Sterilization)**

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By Royal Charter

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 540596**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
CeMed GmbH Im Oberdorf 41 72419 Neufra Germany	**Assembly** **Packaging**
China Biotech Corporation No. 10, 33 rd., Road, Taichung Industrial Park Taichung Taiwan	**Radiation (Gamma Sterilization)**
Degania Silicone Limited Kibbutz 1513000 Degania Bet Israel	**Manufacture**
Donatelle Plastics, Inc. 501 County Road E-2 Extension New Brighton MN 55112 USA	**Manufacture**

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By Royal Charter

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 540596**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Foremount Enterprise Co., Ltd. No. 17, Alley 15, Lane 5 Shenan Street Shengang Dist 42944 Taichung City Taiwan	**Manufacture**
Iotron Industries USA 4394 East Park 30 Drive Columbia City Indiana 46725 USA	**Radiation (E Beam Sterilization)**
Medical Service GmbH Luisenstraße 8 75378 Bad Liebenzell/Unterhaugstett Germany	**Assembly** **Packaging**

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By Royal Charter

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 540596**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Mediplast Israel Ltd. 7 Hayarkon St. P.O. Box 13214 Industrial Zone Yavne 8122710 Israel	**ETO Sterilization**
Rose GmbH für Medizintechnik Gottbillstraße 25-30 54294 Trier Germany	**ETO Sterilization**
sfm medical devices GmbH Brückenstraße 5 63607 Wächtersbach Germany	**ETO Sterilization** **Manufacture**

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By Royal Charter

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 540596**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Sparton Onyx, LLC 2920 Kelly Avenue Watertown South Dakota 57201-7249 USA	**Manufacture**
Sterigenics Germany GmbH Kasteler Straße 45 Wiesbaden 65203 Germany	**ETO Sterilization**
Sterigenics US, LLC 2400 Airport Road Santa Teresa New Mexico 88008 USA	**ETO Sterilization**

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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 540596**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Steritec, Inc. P.O. Box 1969 1705 Enterprise Street Athens, TX 75751 United States of America	**ETO Sterilization**
Synergy Health Sterilisation UK Ltd 1 Alpha Court Capitol Park Thorne Doncaster DN8 5TZ United Kingdom	**ETO Sterilization**
Synergy Sterilisation (M) Sdn Bhd. Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	**ETO Sterilization**

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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 540596**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Teleflex Medical Sdn. Bhd. Lot PT 2577, Jalan Perusahaan 4 34600 Kamunting Perak Malaysia	**ETO Sterilization** **Manufacture**
Viant San Antonio, Inc. 7027 Fairgrounds Parkway San Antonio TX 78238 United States of America	**Manufacture**
Viant Upland, Inc. a.t.a. (formerly) Lake Region Medical 2052 West 11th Street Upland CA 91786 USA	**Manufacture**
Willy Rüsch GmbH Willy-Rüsch-Straße 4-10 71394 Kernen i.R., Germany	**Manufacture**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 540596**

Date: **2020-06-09**

Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
13 January 2009	7245725	First issue.
17 March 2009	7325720	Company address amended. Extension to scope. Addition of Willy Rüsch, Germany as subcontractor for design and manufacture.
25 August 2009	7399908 7439096	Addition of SFM as significant subcontractor for manufacture. Addition of 'design' services supplied by Teleflex Medical, Malaysia, Arrow International CR, a.s. and Arrow International, Inc., Czech Republic. Correction of History page header. Intrauterine catheter added to scope.
08 September 2010	7558507	Scope reworded in accordance with generic device groups. Activity of 'Design' removed from all subcontractors and 'Control of Sterilisation' added. Certificate renewal.

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 540596**
Date: **2020-06-09**
Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
23 February 2011	7635647	Scope extended to include, 'Those aspects of manufacturing relating to securing and maintaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Devices Directive.' Addition of subcontractor, 'ArcRoyal Ltd., Virginia Road, Kells, Co. Meath, Ireland' for Manufacture and Control of Sterilization activities.
23 May 2012	7778468	Correction of significant subcontractor address.
04 February 2013	7932595	The addition of significant subcontractors Foremount Enterprise Co Ltd and Bidoia SAS Di Gianfranco Didia EC.
13 July 2015	8334933	Extension to scope to include 'The manufacture of non-active and active surgical devices for adult and paediatric intraosseous infusion, bone marrow aspiration, bone marrow biopsy and bone lesion biopsy.' Significant subcontractor changes: Addition of Vidacare LLC, Lake Region Medical, Arriol International Corporation, Coastal Life Technologies, Inc & Sparton Onyx. LLC.

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 540596**
Date: **2020-06-09**
Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
28 August 2015	8406492	Certificate renewal. Removal from scope of 'those aspects of Annex V relating to securing and maintaining sterility in the manufacture of non-active digestive tract devices' and 'Those aspects of Annex V related to metrology in the manufacture of non-active respiratory devices'.
10 February 2016	8455693	Removal of Vidacare LLC from list of significant subcontractors. Service(s) supplied for Arriol International Corporation, Coastal Life Technologies Inc. and Lake Region Medical changed from crucial suppliers to Control of Sterilization, Manufacture. Service(s) supplied for Sparton Onyx. LLC changed from crucial supplier to Manufacture. Removal of repeated use of word 'devices' from scope.
28 July 2017	8762518	Change of address for Coastal Life Technologies. Addition of Donatelle Plastics Inc., 55112 New Brighton to list of significant subcontractors.
04 March 2019	7779566	Traceable to NB 0086.

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 540596**
Date: **2020-06-09**
Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
Current	3124053	Certificate renewal. Addition of supplementary product information table. Update to scope to include non-active sterile urology catheters. Name change from Coastal Life Technologies to Viant San Antonio, Inc., Name change from Lake Region Medical to Viant Upland, Inc Removal of Control of Sterilization from Service(s) supplied for ArcRoyal Ltd., Arrow International CR, a.s. (Zdar), Viant San Antonio, Inc., Donatelle Plastics, Inc., Foremount Enterprise Co., Ltd., Viant Upland, Inc., sfm medical devices GmbH, Teleflex Medical Sdn. Bhd., and Willy Rüsch GmbH. Addition of ETO Sterilization to Service(s) supplied for sfm medical devices GmbH and Teleflex Medical Sdn. Bhd. Administrative correction of details for ArcRoyal, Arriol International Corporation, Arrow International CR, a.s., Donatelle Plastics, Inc., Foremount Enterprise Co., Ltd., Sparton Onyx. LLC, sfm medical devices GmbH, Teleflex Medical Sdn. Bhd. and Willy Rüsch GmbH. Removal of Arrow International CR a.s. (Hradec Kralove) and Bidoia SAS Di Gianfranco Didoia E.C. Addition of CeMed GmbH and Medical Service GmbH for Assembly and Packaging.

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 540596**

Date: **2020-06-09**

Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
	3124053	Addition of Degania Silicone Limited for Manufacture Addition of Steritec, Inc., Sterigenics US, LLC, Rose GmbH für Medizintechnik, Synergy Health Sterilisation UK Ltd, Sterigenics Germany GmbH, Mediplast Israel Ltd., and Synergy Sterilisation (M) Sdn Bhd. for ETO Sterilization Addition of Iotron Industries USA for E-beam Sterilization Addition of China Biotech Corporation and BBF Sterilisationsservice GmbH for Gamma Sterilization.

EC Certificate Full Quality Assurance System: US97/10879.01

The management system of

Teleflex Medical

2917 Weck Drive, Research Triangle Park, NC, 27709, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 11 September 2018 until 14 July 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 27 May 2021
Issue 29. Certified since 26 September 2000

Certification is based on reports numbered WWMC/06866

Multiple certificates have been issued for this scope
The main certificate is numbered US97/10879.00

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

Teleflex Medical

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 29

Detailed scope

Sterile Hem-o-lok Ligation Clips.
Sterile Deknatel® PTFE pledgets.
Sterile Polyester Nonabsorbable Surgical Sutures (POLYLENE/ "cottony"™ II, "silky" II POLYDEK®, TEVDEK® II, NextStitch®,Capio™, Fixt®, NiceLoop™, TEVDEK®).
Sterile DEKLENE® II, DEKLENE® MAXXTM, CAPIOTM and FIXT® polypropylene non-absorbable surgical sutures.
Sterile BONDEK® and BONDEK® Plus Polyglycolic Acid Synthetic Absorbable Surgical Sutures.
Sterile Polyglytone 6211™ Monofilament Absorbable Surgical Sutures.
Sterile MONODEK® Polydioxanone Absorbable Surgical Sutures.
Sterile Hem-o-lok Automatic Clip Appliers.
Metal Ligation System.

Sterile External stapling system (including stainless steel staples, staplers and removers), Sterile, EFx endo fascial closuresystem (abdominal access), Sterile, EFx shield fascial closure system (abdominal access), Sterile, EFx classic fascial closuresystem (abdominal access)
Sterile stainless steel surgical Sutures
Sterile FORCE FIBER® surgical sutures.
Sterile Chest drainage and autotransfusion systems,
Sterile Thoracic Catheters,
Sterile and Non-sterile Aortic Punch,
Non-sterile Self Retaining Tissue retractor/blades

Non-sterile Anaesthesia and respiratory Circuits including breathing bags and water traps, Non-sterile Heated Humidifiers, Non-sterile Non-Prefilled Humidifiers and Nebulizers, Non-sterile Small Volume Nebulizers, Sterile Prefilled Humidifiers and Nebulizers (saline or water) with adaptors, Sterile Prefilled unit dose vial /solution for nebulisation, Non-sterile Respiratory therapy Adaptors and connectors, Sterile Column and Reservoirs including adaptors, Non-sterile Nasal cannula (including gas sampling), Non-sterile Cannula and Supply Tubing, Nonsterile CPAP Cannula System, Non-sterile Manual resuscitators and PEEP valves, Non- sterile Respiratory and anaesthesia masks, Non- sterile Gas scavenging mask, Sterile Endotracheal tubes, Sterile Endobronchial tubes, Non-sterile Suction and Aspirating Tubes, Sterile Vented Thoracic Chest Seal, Sterile Operative Cholangiogram Catheters, Sterile Abdominal Access and Insufflation devices, Sterile Capillary drains, Sterile Percutaneous Surgical System (MiniLap and Grip graspers), Sterile Percutaneous Surgical System (Mini Polar electrosurgical probe and MiniGrip Bipolar Graspers),Percutaneous surgical System (Interchangeable electrosurgical tool tips) for laparoscopic surgery. Non-sterile Heat and Moisture Exchangers

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

Certificate US97/10878.00

The management system of

Teleflex Medical

3015 Carrington Mill Blvd., Morrisville, NC, 27560, United States

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 11 September 2018 until 14 July 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 27 May 2021
Issue 20. Certified since 26 September 2000

Multiple certificates have been issued for this scope
The main certificate is numbered US97/10878.00

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

Teleflex Medical

ISO 13485:2016
EN ISO 13485:2016

Issue 20

Detailed scope

Design, development, manufacture and distribution of reusable medical and surgical instruments for general and specialty use; sterile and non-sterile disposable surgical, urology, anaesthesia and respiratory medical devices, sterile disposable electrosurgical medical devices. Design of Non-Sterile Nasal and Oral Mucosal Devices. Design and development of sterile single use absorbable and non-absorbable sutures, pledgets and suture guides and manufacturing of non-sterile absorbable and non-absorbable suture material. Manufacturing of sterile single use absorbable and non-absorbable sutures.

Distribution of sterile single use absorbable and non-absorbable sutures and non-sterile suture material. Distribution of medical devices for endoscopy; fiber optic illuminators; sterile single use instruments for cardiovascular and general surgical procedures.

Additional facilities

375 Forbes Blvd, Mansfield, MA, 02048-1805, United States

2917 Weck Drive, Research Triangle Park, NC, 27709, United States

UKAS MANAGEMENT SYSTEMS
0005

“Endo-Chirurgie” S.R.L.
Codul fiscal: **1009600033242**
Adresa postală: **mun.Chişinău, str. Mesterul Manole, nr. 9.**
Telefon/Fax: (**022) 23-21-33, (022) 66-72-86**

Nr. de ieşire: 43/04 din 13.04.2021

Către: **IMSP Spitalul Raional Orhei**,
Numărul unic de identificare al procedurii de achiziţie:
ocds-b3wdp1-MD-1617872188025/21038278,
”*Consumabilele şi accesoriilor medicale, pentru anul 2021”*.

DECLARAȚIE

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

1. În decurs de 5 (cinci) zile de la solicitarea autorităţii contractante/beneficiarului/organizatorului licitației, va prezinta mostre.

2. Termenul de valabilitate restant (la momentul livrării) va constitui 80% din termenul total al produsului dar, nu mai mic de 12 luni.

3. În cazul în care oferta companiei va fi declarată cîştigătoare, la livrare va prezenta Extras din Registru de Stat a dispozitivelor medicale, pentru pozițiile care se supun înregistrării.

4. În cazul în care oferta companiei va fi declarată cîştigătoare, în conformitate cu prevederile legale în vigoare, va prezenta declarația privind confirmarea identității beneficiarilor efectivi și neîncadrarea acestora în situația condamnării pentru participarea la activități ale unei organizații sau grupări criminale, pentru corupție, fraudă și/sau spălare de bani.

Cu respect,
Specialist achiziții publice, Juristconsult **Pavel DUBALARI**

"Endo-Chirurgie" S.R.L.
Codul fiscal: **1009600033242**
Adresa postală: **mun.Chișinău, str. Meșterul Manole, nr. 9.**
Telefon/Fax: **(022) 23-21-33, (022) 66-72-86**

ORDIN nr. 25

„De imputernicire a persoanei"

Din 01 septembrie 2020

Întru desfășurarea continuă și corectă a procesului de întocmire a documentelor pentru participarea în cadrul procedurilor de achiziții publice, organizate de către Autoritățile Contractante din Republica Moldova, în cazul absenței mele de la locul de lucru,

ORDON:

A împuternici dl **DUBALARI Pavel**, IDNP: **2001003326049**, angajat în calitate de jurisconsult, pentru ca în numele meu să:

1. Semneze oferta, precum și toate actele aferente procedurilor de achiziții, inclusiv prin aplicarea semnăturii sale electronice (digitală).
2. În caz de necesitate va aplica ștampila pe actele menționte mai sus.

Director „Endo-Chirurgie" S.R.L. **GHEREG Victor**

Luat la cunoștință **DUBALARI Pavel**