Specificaţii tehnice

Numărul procedurii de achiziție: ocds-b3wdp1-MD-1705667688733
Obiectul achiziției: Instrumente medicale 2024

Nr. Lot	Denumirea bunurilor/serviciilor	Denumirea modelului bunului/serviciului	Ţara de origine	Producătorul	Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către ofertant	Standarde de referinţă
	1	2	3	4	5	6	7
1	Forceps pentru biopsie	GF230S	Belgia	G-Flex	Forceps pentru biopsie, flexibil. Lungimea 200 - 220 cm, Muchia de tŇiere a maxilarului netedŇ, cu ac. Grosime 2,4 mm Posibilitate de utilizare ŭi sterilizare multiplŇ	Forceps pentru biopsie, flexibil. Lungimea 200 - 220 cm, Muchia de tŇiere a maxilarului netedŇ, cu ac. Grosime 2,4 mm Posibilitate de utilizare ŭi sterilizare multiplŇ	CE, ISO

Semnat: Numele, Prenumele: Gheorghe Bunic În calitate de: Director

Ofertantul: Ericon SRL Adresa: Chișinău; or. Durlești; str. Vasile Lupu; nr.6; Republica Moldova

Digitally signed by Bunic Gheorghe
Date: 2024.01.25 21:52:51 EET
Reason: MoldSign Signature
Location: Moldova

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Land/Pays/Land	***BELGIË - BELGIQUE - BELGIEN***
2. Deze openbare akte is ondertekend door : Le présent acte a été signé par : Diese öffentliche Urkunde ist unterschrieben von :	***Vlaminck Frederik***
3. Handelend in hoedanigheid van : Agissant en qualité de : In seiner/ihrer Eigenschaft als :	***Notaris/Notaire/Notar***
4. Is voorzien van het zegel van : Est revêtu du sceau de : Sie ist versehen mit dem Siegel des/der :	***Johan KIEBOOMS & Frederik VLAMINCK, Geassocieerde notarissen***

Voor echt verklaard / Attesté / Bestätigt

5. ***Te Brussel/A Bruxelles/In Brüssel***	6. Op/Le/Am : ***23/06/2021***

7. Door FOD Buitenlandse Zaken, Buitenlandse Handel en Ontwikkelingssamenwerking
Par le SPF Affaires étrangères, Commerce extérieur et Coopération au Développement
Durch FÖD Auswärtige Angelegenheiten, Außenhandel und Entwicklungszusammenarbeit

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VICTORIABANK
PRIMA BANCĂ DIN MOLDOVA

Filiala nr. 8 Chişinău
Bd. Decebal, 99
MD-2060, mun. Chişinău
Republica Moldova
Tel.: (+373 22) 57-48-00
Fax: (+373 22) 53-05-12
SWIFT: VICBMD 2X802
IDNO 1002600001338
Capital social - 250 000 910 lei
www.victoriabank.md

Nr. 140 din "2" februarie 2016

La Nr. _____ din "_____" _____ 201 mun. Chişinau

C E R T I F I C A T

Eliberat agentului economic ERICON SRL, cod fiscal 1003600000316 cu sediul în Republica Moldova, mun. Chişinau, str. Zelinski 15, precum că deţine cont curent în MDL nr. MD60VI222400008100401MDL, EUR MD39VI0002224017081004O1EUR, USD MD14VI0002224001081004O1USD şi RUB MD36VI0002224050081004O1RUB la Filiala nr.8 Chişinau BC "Victoriabank" SA, codul băncii VICBMD2X802.

Director Filiala nr. 8
BC "Victoriabank" SA — *M. Bartcovschi*

Contabil-şef al filialei nr.8
BC "Victoriabank" SA — *S. Talpa*

Executor: Siniucova Elena
Tel: 022 57-48-12

I.P. "AGENŢIA SERVICII PUBLICE"
Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS
din Registrul de stat al persoanelor juridice

nr. **39071** din **22.12.2020**

Denumirea completă: **Societatea cu Răspundere Limitată «ERICON» .**
Denumirea prescurtată: **«ERICON» S.R.L. .**
Forma juridică de organizare: **Societate cu Răspundere Limitată.**
Numărul de identificare de stat şi codul fiscal: **1003600000316.**
Data înregistrării de stat: **20.10.1992.**
Sediul: **MD-2003, str. Vasile Lupu, 6, or. Durleşti, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1 Editarea cărţilor, broşurilor şi altor publicaţii;
2 Tipărirea ziarelor;
3 Publicitate;
4 Comerţul cu amănuntul al cărţilor, ziarelor şi rechizitelor de birou;
5 Comerţul cu amănuntul al articolelor medicale şi ortopedice.
Capitalul social: **449852** lei.
Administrator: BUNIC GHEORGHE,
Asociaţi:
1. BUNIC GHEORGHE 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 şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: 22.12.2020.

Specialist coordonator
tel. 022-20-7838

Clichici Elena

INSTITUŢIA PUBLICĂ "AGENŢIA SERVICII PUBLICE" IDNO 1002600034700 REPUBLICA MOLDOVA CHIŞINĂU 003

Date cu caracter personal. Operator: I.P. "Agenţia Servicii Publice" IO 0000059

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APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Land/Pays/Land: ***BELGIË - BELGIQUE - BELGIEN***

2. Deze openbare akte is ondertekend door :
Le présent acte a été signé par :
Diese öffentliche Urkunde ist unterschrieben von : ***LEFEVRE Sophie***

3. Handelend in hoedanigheid van :
Agissant en qualité de :
In seiner/ihrer Eigenschaft als : ***Notaris/Notaire/Notar***

4. Is voorzien van het zegel van :
Est revêtu du sceau de :
Sie ist versehen mit dem Siegel des/der : ***Sophie LEFEVRE***

Voor echt verklaard / Attesté / Bestätigt

5. ***Te Brussel/A Bruxelles/In Brüssel*** 6. Op/Le/Am : ***20/06/2023***

7. Door FOD Buitenlandse Zaken, Buitenlandse Handel en Ontwikkelingssamenwerking
Par le SPF Affaires étrangères, Commerce extérieur et Coopération au Développement
Durch FÖD Auswärtige Angelegenheiten, Außenhandel und Entwicklungszusammenarbeit

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G-Flex Europe Srl
Rue de l'Industrie 20
1400 Nivelles
Belgium

26 Apr 2023

Confirmation Letter Reference: CLNB1639 – BE/AND/23/1285.QMD

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

G-Flex Europe Srl
Rue de l'Industrie 20
1400 Nivelles
Belgium
SRN Number: BE-MF-000000623

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15th March 2023, this letter also confirms that:

- The manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices

- 31st December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,

On behalf of G-Flex Europe SPRL

pp [Jérôme JADOT]

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Thierry CREMER
QA/RA Director & PRRC
Email: thierry@g-flex.com
Phone +32495548870
84, Drève de l'Infante
1410 Waterloo

Devices covered by this letter:

Device name / Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Endoscopic Drainage Stent & Application System 54200513-TF01-STT-SU-NT (Part of MDR file Sterile Biliary & Pancreatic Stents)	Class IIb implantable non-WET device	N/A	BE19/819943763 (Issue 5), CE1639 93/42/EEC – Annex-II

Sophie LEFEVRE - Notaire - Mont sur Marchienne

Vu pour légalisation de la signature de Monsieur Thierry CREMER, apposée ci-dessus, par Maître Sophie LEFEVRE, Notaire à Mont-sur-Marchienne, en date du 20 juin 2023.