Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin 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 6000 6226, e-mail corneliu@ericon.md,
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- G-FLEX 525TL-M
- G-FLEX K18NTL

Se anexează următoarele acte:

a) declarația de conformitate CE emisă de producător pentru dispozitivul medical fabricat;

b) certificatul de conformitate CE valabil pentru dispozitivele fabricate, după caz;

c) actul prin care producătorul își desemnează reprezentantul.

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 SRL cu sediul or. Durlesti, str. Vasile Lupu, nr. 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:

- G-FLEX 525TL-M
- G-FLEX K18NTL

Sunt autentice și corespund realității.

Corneliu Bunic *Semnătura* _____

Data _____

Authorisation Letter

30 November 2022

To whom it may concern,

We, G-Flex Europe SPRL, based in 20, Rue de l'Industrie, 1400 - Nivelles, Belgium,

assign ERICON SRL, based in 6, Vasile Lupu str. Durlești, Chisinau. Republic of Moldova

as **authorized representative** in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC or 90/385/EEC.

We declare that the company mentioned above is authorized to 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.

Nivelles,

QA/RA Director & PRRC

EC Certificate Full Quality Assurance System: Certificate BE19/819943763

The management system of

G-Flex Europe Sprl

Rue de l'Industrie 20
1400 Nivelles, Belgium

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

Multiband Ligator, non-sterile disposable device for the treatment of oesophageal varices.
Sterile Non-Vascular Guidewires
Sterile Extraction Baskets & lithotripsy system
Sterile Disposable Hemoclip system
Sterile Disposable Biopsy Forceps
Sterile Disposable Endoscopic Forceps & Retrievers
Sterile Stone Extraction Balloon Catheter
Sterile Dilation Balloon Catheter
Sterile Cysto-Gastro Sets
Sterile Sphincterotomes / Papillotomes
Sterile Disposable Polypectomy Snares
Sterile Endoscopic Drainage Stents & Application Systems

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.

This certificate is valid from 25 May 2021 until 01 June 2023
and remains valid subject to satisfactory surveillance audits.
Issue 5. Certified since 01 April 2013

Certification is based on reports numbered BE/AND 12/1285.QMD

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

Seen for legalization of
the signature of
De Vincker
Geofray
Antwerpen, 22/06/21

CE Certificate Extension Letter

13 June 2023

To whom it may concern,

We, the company, G-Flex Europe SPRL, hereby declare that the products listed in the table below are classified medical device, in accordance with annex IX of Directive 93/42/EEC.
Those products are covered by the attached CE certificate that according to Regulation EU 2023/607 amending Regulation EU2017/745 is extended to the period shown on the table below.
This is confirmed by our Notified Body (SGS Belgium - CE1639) with the subjoined letter referenced: CLNB1639 - BE/AND/23/1285.QMD.

TF#	Description	Classification under MDD	MDD Certificate	Extension Period
01	Endoscopic Drainage Stent & Application System	IIb implantable	BE19/819943763	31 December 2027
08	Disposable Hemoclip	IIb non-implantable	BE19/819943763	31 December 2028
02	Cysto-Gastro Sets	IIb non-implantable	BE19/819943763	31 December 2028
12	Sphrincterotomes Papillotomes	IIb non-implantable	BE19/819943763	31 December 2028
09	Disposable Polypectomy Snares	IIb non-implantable	BE19/819943763	31 December 2028
05	Multiband Ligator	IIa	BE19/819943763	31 December 2028
11	Non-Vascular Guidewire	IIa	BE19/819943763	31 December 2028
14	Disposable Biopsy Forceps	IIa	BE19/819943763	31 December 2028
13	Stone Extraction Balloon Catheter	IIa	BE19/819943763	31 December 2028
03	Dilation Balloon Catheter	IIa	BE19/819943763	31 December 2028
04	Disposable Endoscopic Forceps & Retrievers	IIa	BE19/819943763	31 December 2028
07	Disposable Extraction Basket & Lithotripsy System	IIa	BE19/819943763	31 December 2028

The quality control and conformity assessment procedures are carried out in accordance with the harmonized standard ISO 13485, audited by the notified SGS Belgium (CE1639) and attested by a certificate (Réf. BE19/819943763)

A complete quality assurance system (ISO 13485) has been set up at G-Flex Europe SPRL, audited, in accordance with Directive 93/42/EEC, Annex II, without point 4, by the notified body SGS Belgium and attested by a certificate (Ref BE21/819944170).

This declaration is valid from 13-06-2023, for all the products mentioned above.

QA/RA Director & PRRC
84, Drève de l'infante - 1410 Waterloo

G-Flex Europe SPRL - Simple & Performing - VAT: BE0876.308.490 - Certified ISO 13485

Vu pour légalisation conforme de la signature devant le Notaire Sophie Lefèvre notaire à Mont sur Marchienne, A destination du Brésil

13/06/2023

Sophie LEFEVRE - Notaire - Mont sur Marchienne

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.

Declaration of Conformity

Manufacturer:	G-Flex Europe SPRL
Single Registration Number (SRN):	BE-MF-000000623
Address:	20, Rue de l'industrie 1400 - Nivelles, Belgium
Product Name:	Sphincterotomes/Papillotomes
Basic UDI-DI:	54200513-TF12-SPH-SU-JP
Classification:	Class IIb, Rule 9
Conformity assessment route:	MDD Annex II Excluding Article 4
Models:	See attachment

G-Flex Europe SPRL declares on our own responsibility that the medical devices describe above are in conformity with the requirements of Council Directive 93/42/EEC of June 14, 1993 (MDD) as amended by Directive 2007/47/EC and of its transpositions in national laws. They are covered by an extended CE certificate in accordance with Regulation EU 2023/607 amending Regulation EU 2017/745 and are in conformity with the relevant harmonized standards EN 1041:2008/A1:2013; EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN ISO 13485:2016; EN ISO 14971:2019; EN ISO15223-1:2016; MEDDEV 2.7-1/Rev.4; ISO 2859-1:1999; ASTM F1980-16; EN 556-1:2001; EN ISO 10993-7:2008; EN ISO 11607-1:2017; EN ISO 11607-2:2017; EN ISO 11737-2:2009; EN ISO 14644-1:2015; EN ISO 14644-2:2015; ISO 11135:2014; ISO 11138-1:2017; ISO 11138-2:2017; ISO 11737-1:2018; DIN 13273-7:2003; DIN EN 1618:1997; EN 60601-1:2005/AMD1:2012; IEC 60601-2-2:2017; EN 60601-1-6:2010; ISO 80369-7:2016.

This statement of conformity is only valid in connection with a signed Delivery Note for the respective Lot number of produced devices.

The device fulfill the essential requirements of Annex I of the MDD.

Notify Body:	SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp - Belgium
NB identification number:	1639
Expiry Date:	31/12/2028 as Confirmed by the Extension Letter CLNB1639 - BE/AND/23/1285.QMD
Place and date of issue:	Nivelles, 26/06/2023

G-Flex Europe SPRL – Simple & Performing
VAT: BE0876.308.490 Certified ISO 13485

Thierry CREMER - QA/RA Director and PRRC

Declaration of Conformity

Attachment

Product Name: Sphincterotomes/Papillotomes

Basic UDI-DI: 54200513-TF12-SPH-SU-JP

Reference	UDI-DI	GMDN	GMDN Term
520TL	5420051302499	65185	ERCP catheter, non-balloon, electrosurgical
520TL-MR	5420051307425	65185	ERCP catheter, non-balloon, electrosurgical
520TL-SW	5420051306312	65185	ERCP catheter, non-balloon, electrosurgical
525TL-M	5420051306343	65185	ERCP catheter, non-balloon, electrosurgical
525TL-MSWR	5420051306350	65185	ERCP catheter, non-balloon, electrosurgical
530TLSC	5420051300303	65185	ERCP catheter, non-balloon, electrosurgical
GW08-000HF	5420051303380	65185	ERCP catheter, non-balloon, electrosurgical
K18NTL-SW	5420051306374	65185	ERCP catheter, non-balloon, electrosurgical

Reference	UDI-DI	GMDN	GMDN Term
520TL-M	5420051306329	65185	ERCP catheter, non-balloon, electrosurgical
520TL-MSWR	5420051306336	65185	ERCP catheter, non-balloon, electrosurgical
525TL	5420051300280	65185	ERCP catheter, non-balloon, electrosurgical
525TL-MR	5420051306534	65185	ERCP catheter, non-balloon, electrosurgical
525TL-SW	5420051306367	65185	ERCP catheter, non-balloon, electrosurgical
530TLSC-MR	5420051306695	65185	ERCP catheter, non-balloon, electrosurgical
K18NTL	5420051302925	65185	ERCP catheter, non-balloon, electrosurgical

Numarul de catalog	Denumire	Denumirea comerciala	Modelul	Tip dispozitiv	Cod GMDN
525TL-M	Sphincterotomes/Papillotomes	G-Flex Sphincterotomes/Papillotomes	525TL-M	Sphincterotomes/Papillotomes	65185
K18NTL	Sphincterotomes/Papillotomes	Sphincterotomes/Papillotomes	K18NTL	Sphincterotomes/Papillotomes	65185