

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	
8. Onder Nr./Sous le n°/Unter Nr. : 230624192760	
9. Stempel/Sceau/Stempel:	10. Ondertekening/Signature/Unterschrift:
	

Prijs/Prix/Preis: **20.00** EUR

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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	Ilb implantable	BE19/819943763	31 December 2027
08	Disposable Hemoclip	Ilb non-implantable	BE19/819943763	31 December 2028
02	Cysto-Gastro Sets	Ilb non-implantable	BE19/819943763	31 December 2028
12	Sphincterotomes Papillotomes	Ilb non-implantable	BE19/819943763	31 December 2028
09	Disposable Polypectomy Snares	Ilb non-implantable	BE19/819943763	31 December 2028
05	Multiband Ligator	Ila	BE19/819943763	31 December 2028
11	Non-Vascular Guidewire	Ila	BE19/819943763	31 December 2028
14	Disposable Biopsy Forceps	Ila	BE19/819943763	31 December 2028
13	Stone Extraction Balloon Catheter	Ila	BE19/819943763	31 December 2028
03	Dilation Balloon Catheter	Ila	BE19/819943763	31 December 2028
04	Disposable Endoscopic Forceps & Retrievers	Ila	BE19/819943763	31 December 2028
07	Disposable Extraction Basket & Lithotripsy System	Ila	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'enfante - 1410 Waterloo


vu par l'extension conforme de la signature devant le Notaire Sophie Lefèvre Notaire à Mont sur Marchienne, A destination du Brésil

 13/06/2023

Related SOP: SOP-Administrative Documents
 Original Form: F-Authorization Letter
 Current Name: F-Authorization Letter

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