

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

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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. : 230622832882	
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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-F/EX Europe SPRL



pp [Jérôme JADOT]

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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

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.