



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

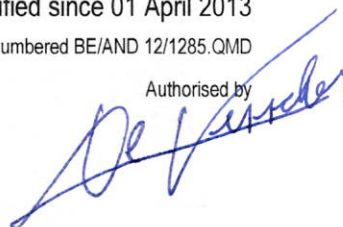
Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

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



Seen for legalization of
the signature of

De Vincher

Geofray

Global Medical Devices Head of Notified Body

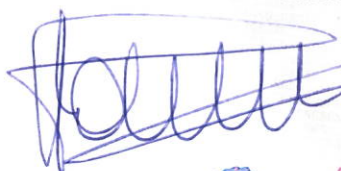
SGS Belgium NV, Notified Body 1639

Antwerpen, 22/06/21

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

Page 1 of 1


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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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