

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**

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 16 December 2019 until 01 June 2023 and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 01 April 2013 and first certified by SGS Belgium NV since 16 December 2019

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

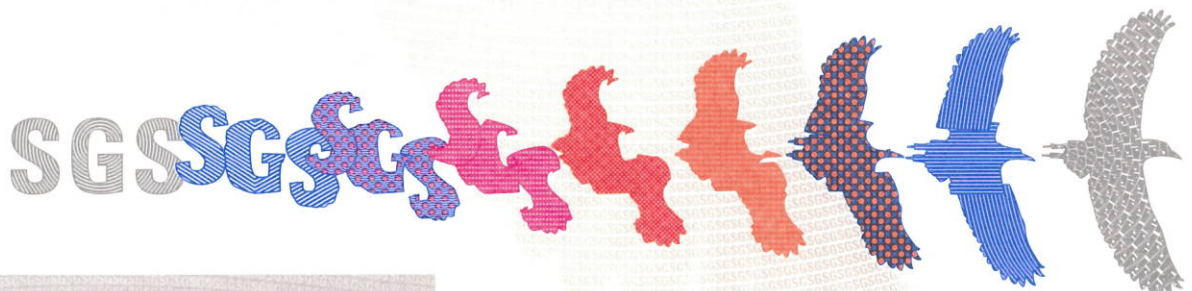
Authorised by

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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

declares on our own responsibility that the medical device:

Product	Reference	Class	Rule
MULTIBAND LIGATOR	GF-OVL100-V2, GF-OVL200, GF-OVL200-RL, GF-OVL200-V2, GF-OVL300-V2, GF-OVL510, GF-OVL501-V2, GF-OVL100-LF, GF-OVL100-V3, GF-OVL100-LF-V2, GF-OVL300, GF-OVL501, GF-OVL100, GF-OVL510-V2, GF-OVL100-LC-01, GF-OVL100-R, GF-OVL100-RU	I	5

are in conformity with the requirements of Council Directive 93/42/EEC of June 14, 1993 (MDD) and of its transpositions in national laws. This statement of conformity is only valid in connection with a signed Delivery Note for the respective Lot number of produced devices.

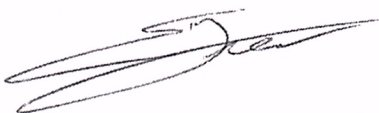
The device fulfill the essential requirements of Annex I of the MDD.

The conformity assessment procedure was established in accordance with:

Notify Body	SGS United Kingdom Limited Unit 202B, Worle Parkway, Weston-super-Mare, Somerset, BS22 6WA - United Kingdom
Identificaton Number	0120
Procedure	Article 10 of the Belgian Royal Decree of March 18th 1999 on Medical Devices

The device are manufactured in the European Union.

Nivelles, 12/12/2014



Thierry CREMER
Quality Manager

