simple and performing
www.g-flex.com

Declaration of Conformity

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.

Digitally signed by Bunic Gheorghe
Date: 2020.01.18 21:09:08 EET
Reason: MoldSign Signature
Location: Moldova

Nivelles, 12/12/2014

Thierry CREMER
Quality Manager

G-Flex Europe Sprl - Simple & Performing
ISO 9001
www.g-flex.com
ISO 13485
VAT: BE0876.308.490

Certificate BE19/819943488

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

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, development, manufacture and sales of non-active and active (non-implantable) medical devices and accessories for application in endoscopy and respiratory.

Distribution of non-active and active (non-implantable) medical devices for application in endoscopy, urology and respiratory.

This certificate is valid from 22 May 2019 until 01 June 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 01 May 2021
Issue 2. Certified since 19 April 2019

Authorised by

SGS United Kingdom Ltd
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HC SGS 13485 2016 0118

UKAS MANAGEMENT SYSTEMS
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