Digitally signed by Bunic Gheorghe
Date: 2019.11.03 22:17:45 MSK
Reason: MoldSign Signature
Location: Moldova

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.

Nivelles, 12/12/2014

Thierry CREMER
Quality Manager

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

Certificate BE13/223575066

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 13485:2003
EN ISO 13485:2012

For the following activities

Design and development, manufacture and distribution of sterile and non-sterile instruments and accessories for applications in endoscopy, urology and respiratory.

This certificate is valid from 3 September 2015 until 1 June 2018 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 1 May 2018.
Issue 5. Certified since 1 April 2013.

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

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SGS 13485-2 1114