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.

Nivelles, 12/12/2014

Thierry CREMER
Quality Manager

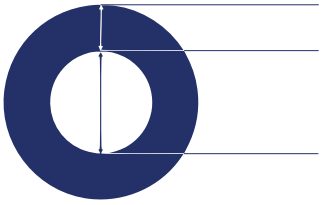
G-Flex Europe Sprl - Simple & Performing
ISO 9001
www.g-flex.com
ISO 13485
1003876.308.490

Digitally signed by Bunic Gheorghe
Date: 2019.04.16 16:07:18 EEST
Reason: MoldSign Signature
Location: Moldova

Multi-Band Ligator

/Ligateur à élastiques /Ligador de Multibandas

Reference Réf. / Ref.	CATHETER CATHÉTER / CATÉTER Length (cm) Long. / Longitud	CATHETER CATHÉTER / CATÉTER Diam. (mm) Diam. / Diám.	Quantity (shots) Quantité (tirs) / Cantidad (Disparos)	RING ANNEAU / ANILLO Internal diam. in released position (mm) Diam. interne en position relâchée Diám. Interno una vez suelto el anillo	RING ANNEAU / ANILLO Thickness in released position (mm) Epaisseur en position relâchée Espesura una vez suelto el anillo	ENDOSCOPE ENDOSCOPE / ENDOSCOPIO Diam.(mm) Diam. / Diám.	Price Prix / Precio
GF-OVL100	150	2.2	6 latex	1.90	1.75	8.5-11.5	
GF-OVL100-LF	150	2.2	6 latex-free	1.95	1.90	8.5-11.5	
GF-OVL501	150	2.2	7 latex	1.90	1.75	8.5-11.5	
GF-OVL510	150	2.2	10 latex	1.90	1.75	8.5-11.5	



Thickness in released position
/Epaisseur de la bande élastique après largage
/Espesor de la banda una vez disparada

Internal diam. in released position
/Diamètre interne de la bande élastique après largage
/Diámetro interno de la banda una vez disparada

EZY® Shoot

Pre-loaded guiding catheter for easy mounting
/Cathéter guide pré-monté pour un montage facile /Catéter guía pré cargado para fácil montaje

Universal luer-lock connection for cleaning
/Connexion luer-lock universelle pour nettoyage /Conexión universal luer-lock para lavado

Silicone ring for better suction
/Anneau en silicone pour une meilleure succion /Anillo en silicona para mejor succión

Can be mounted on all endoscopes
/Peut être monté sur tous les endoscopes /Puede ser montado en todas las marcas de endoscopio

Yellow color code ring for quick indentification of the last shot
/Code couleur jaune de l'anneau pour une identification rapide du dernier tir
/Código color amarillo para fácil identificación del último disparo

Available in 6, 7, 10 latex and 6 latex-free shots
/Disponible en 6, 7, 10 en latex et 6 tirs sans latex
/Disponible en 6, 7, 10 disparos en latex y 6 disparos libre de latex

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 9 March 2016 until 1 June 2020 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 1 May 2018.
Issue 7. Certified since 1 April 2013.

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

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
SGS United Kingdom Ltd Systems & Services Certification
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SGS CE 02 0315 M2

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