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

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

Digitally signed by Bunic Gheorghe
Date: 2021.04.07 09:30:49 EET
Reason: MoldSign Signature
Location: Moldova

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 **f** +32 (0)3 545-48-49 www.sgs.com

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
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