EC Certificate Full Quality Assurance System: BE13/223575069

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

The scope of registration appears on page 2 of this certificate.

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
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

G-Flex Europe Sprl

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 7

Detailed scope

Sterile Amplatz Renal Dilator Set
Sterile Amplatz Sheath for maintaining nephrostomy tract

Sterile Biliary, Cysto & Pancreatic Stents
Sterile Biliary prosthesis
Sterile Biopsy Valves
Sterile Coagulation Probes
Sterile Cysto-gastro Sets
Sterile Cytology Brushes

Sterile Dilation balloon
Sterile Disposable Biopsy Forceps
Sterile Disposable Foreign Body Retrievers
Sterile Disposable Hot Biopsy Forceps
Sterile Disposable Polypectomy Snares
Sterile Endoscopic drainage stent
Sterile Grasper Forceps
Non-sterile Hot Biopsy Forceps
Sterile Mucosectomy Snares
Sterile Nasal Biliary Drainage
Sterile Non-vascular Guidewires
Sterile Oesophageal Stents (Self Expandable, Nitinol)
Sterile Punction Needles
Sterile Sclerotherapy & Injection Needles
Sterile Sphincterotomes / Papillotomes
Sterile Spray Catheters
Sterile Disposable Hemoclip
Sterile Stone Extraction balloon Catheter
Sterile Stone Retrieval Baskets
Sterile Ultrasonic Aspration Needles
Sterile Uretheral Catheters
Sterile Ureteral Stents

Multiband Ligator, non sterile disposable device for the treatment of oesophageal varices.

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