EC Certificate Production Quality Assurance System: Certificate
BE13/223575068

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 V
Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.

For the following products

Sterile Biliary Dilation Catheters
Sterile Disposable E.R.C.P. Catheters
Sterile Disposable Extraction Baskets
Sterile Endoscopic Needle
Sterile Guide Wires
Sterile Guiding Catheters, Pushers, Stent Application Systems
Sterile Mechanical Lithotriptors
Sterile Ureteral Access Sheath

This certificate is valid from 3 September 2015 until 1 June 2020 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 1 May 2018.
Issue 3. 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
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
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SGS CE 18 0811

EC Certificate Production Quality Assurance System: Certificate
BE13/223575067

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 V

For the following products

Sterile Cold Snares

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

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Re certification audit due before 1 May 2018.
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