

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

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