EC Certificate Production Quality Assurance System: Certificate GB97/11156

The management system of

Pelican Feminine Healthcare Limited
also trading as Single Use Surgical

Cardiff Business Park, Llanishen, Cardiff, CF14 5WF, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC
on medical devices, Annex V

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 03 December 2018 until 02 August 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 02 August 2020
Issue 21. Certified since 17 October 1997

Certification is based on reports numbered GB/PC 02665

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
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SGS CE 13 0311 M2

Pelican Feminine Healthcare Limited
also trading as Single Use Surgical

Directive 93/42/EEC
on medical devices, Annex V

Issue 21

Detailed scope

Sterile Pelijelly Hydrogel for use as a lubricant in gynaecological, digital and instrument examinations.

Sterile Pulse Lavage System.

Annex V Sterility aspects only - restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:

Sterile Scissor Devices, Disposable Vaginal Specula.
Sterile Disposable Specula Light Source Lead.
Sterile Disposable Proctoscopes.
Sterile Disposable Instruments for Gynaecological use.
Sterile Disposable Examination Instruments.
Sterile IUD Fitting and Removal Kits.

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.