

The management system of

Pelican Feminine Healthcare Limited

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

Annex V

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

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

**Sterile Vaginal Specula.
Sterile Disposable Proctoscopes.
Sterile Instruments for Gynaecological use.
Sterile Disposable Examination Instruments.
Sterile IUCD Fitting and Removal Kits.**

For placing on the market of Class IIb or Class III devices covered by this certificate, an EC Type Examination Certificate according to Annex III is required.

This certificate is valid from 01 December 2014 until 02 August 2019 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 02 August 2017
Issue 15. Certified since 17 October 1997

Certification is based on reports numbered GB/PC 02665

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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

SGS CE 13 0311

Page 1 of 1

