

Pelican Feminine Healthcare Limited
also trading as **Single Use Surgical**



ISO 13485:2016
EN ISO 13485:2016

Issue 21

Detailed scope

Design and manufacture of:

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

Sterile pelispec smoke extraction speculum

Sterile and non-sterile Scissor Devices,

Sterile and non-sterile Disposable Vaginal Specula.

Sterile and non-sterile Disposable Specula Light Source Lead.

Sterile and non-sterile Disposable Proctoscopes.

Sterile and non-sterile Disposable Instruments for Gynaecological use.

Sterile IUD Fitting and Removal Kits

Sterile Pulse Lavage System

**Sterile and non-sterile single use non-cannulated instruments for ENT, General,
Gynaecology, Ophthalmology, Oral and Maxillofacial, Orthopaedic,
Paediatric and Spinal Surgeries Sterile Spackmann Cannula,**

Sterile and non-sterile Suction Irrigator,

Sterile and non-sterile Suction Tubes for general Surgical use,

Sterile Diathermy Suctions

**Provision of contract ethylene oxide processing services
in accordance with ISO11135:2014.**



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Certificate GB02/56692

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

ISO 13485:2016 EN ISO 13485:2016

For the following activities

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

This certificate is valid from 03 December 2018 until 02 August 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 02 August 2020
Issue 21. Certified since 02 August 2002

Authorised by



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