Certificate GB96/7943

The management system of

Femcare Limited

32 Premier Way, Romsey, SO51 9DQ, 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 21 November 2021 until 21 November 2024
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 26. Certified since 23 August 1996

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

21HC 13485 2016 0421 M2

Femcare Limited

ISO 13485:2016
EN ISO 13485:2016

Issue 26

Detailed scope

Design, manufacture and distribution of:

Sterile implantable Filshie® Clip (Tubal Ligation Clip for Female Sterilization)

Sterile single use Applicators (Sterishot II, Sterishot II for Minilaparotomy) for use with Filshie® Clip

Sterile single use Filshie® Clip System (Filshie Clip and Applicator Kits)

Sterile hormone replacement therapy procedure trays

Sterile trocar cannula obturators for hormone replacement therapy

FempacTM Sterile femoral canal sponge

Add-a-Cath® Sterile suprapubic catheter introducer and kits

Sterile replacement cannula seals

Non sterile non scalpel vasectomy kits, clamps and forceps

Design, manufacture, distribution and servicing of non-sterile reusable Applicators for use with Filshie® Clip and Classic Trocar & Cannula

Distribution of non-active medical devices and active medical devices (non-implantable)

For the areas of gynaecological, urological, orthopaedic and general surgical procedures.

UKAS MANAGEMENT SYSTEMS
0005

EC Certificate Full Quality Assurance System: Certificate GB19/964837

The management system of

Femcare Limited

32 Premier Way, Romsey, Hampshire, SO51 9DQ, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Sterile implantable Filshie® Clip
(Tubal Ligation Clip for Female Sterilization).
Sterile single use Applicators
(Sterishot II, Sterishot II for Minilaparotomy) for use with Filshie® Clip.
Sterile hormone replacement therapy procedure trays
Sterile trocar cannula obturators for hormone replacement therapy
FempacTM sterile femoral canal sponge
Add-a-Cath® sterile suprapubic catheter introducer
Sterility aspects only – restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:
Sterile replacement cannula seals.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 12 February 2020 until 21 November 2023
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 23 August 1996
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered GB/PC 05202

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

EC Design Examination Certificate: Certificate GB20/965024

Femcare Limited

32 Premier Way SO51 9DQ Romsey, United Kingdom

Device Identification:

Filshie™ Tubal Ligation System

Intended Purpose of Device:

Sterile contraceptive tubal occlusion devices for permanent female sterilization by occlusion of the Fallopian tubes

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices, Annex II, Section 4

It is certified that the manufacturer's design dossier (and product, where applicable) for the above device has been examined and, based on the evidence submitted, it is considered that the device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjunction with a certificate covering the full quality assurance system to Annex II, which must be subject to satisfactory surveillance audits.

This certificate is valid from 16 December 2019 until 07 July 2023
Issue 1. Certified since 07 July 1998
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered GB/PC 201988

Certification is based on reports numbered GB/PC 201988 dated 31 August 2018

Addenda to that report have been issued on the following dates:

Addendum Date	Reason for Addendum
27 September 2019	Change of company name
-	

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com