Medical Device Full Quality Assurance System Certificate
GB24/00000019

The management system of

# Femcare Limited

32 Premier Way Romsey Hampshire SO51 9DQ United Kingdom

has been assessed and certified as meeting the requirements of

**Part II of The Medical Devices Regulations 2002, Annex II excluding section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]**

For the following products
**The Scope of Registration appears on page 2 of this certificate**

This certificate is valid from 09 July 2024 until 24 January 2029 and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 24 January 2024

L. Henderson

Authorised by
Lynn Henderson

SGS United Kingdom Ltd Approved Body 0120
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 - www.sgs.com

Medical Device Full Quality Assurance System Certificate
GB24/00000019, continued

# Femcare Limited

## Part II of The Medical Devices Regulations 2002, Annex II excluding section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

Issue 2

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 Design Examination Certificate according to Annex II (Section 4) [as modified by Part 2 of Schedule 2A of The MDR 2002] is a mandatory requirement for each device in addition to this certificate to place that device on the market

Certification is based on reports numbered GB/PC/05202
Previous certificate number: N/A
Change in between this certificate and previous one: Removal of Sterile implantable Filshie® Clip (Tubal Ligation Clip for Female Sterilization) class III from certificate scope

Certificate GB96/7943

The management system of

# Femcare Limited

32 Premier Way Romsey Hampshire SO51 9DQ United Kingdom

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 15 November 2024 until 24 January 2027 and remains valid subject to satisfactory surveillance audits.
Issue 28. Certified since 23 August 1996

L. Moran

Authorised by
Liz Moran
Business Manager

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

# Femcare Limited

## ISO 13485:2016
## EN ISO 13485:2016

Issue 28

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.

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

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

Certificate GB21/969292

The quality management system of

# Femcare Ltd.

32 Premier Way Romsey Hampshire SO51 9DQ United Kingdom
Facility number: F003731

has been assessed and certified as meeting the requirements of

## MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System

Brazil: RDC ANVISA n. 665/2022 - Good Manufacturing Practices; RDC ANVISA n. 551/2021; RDC ANVISA n. 67/2009 - Vigilance
Canada: Medical Device Regulations SOR/98-282, Part 1
USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation, 21 CFR Part 821 - Device Tracking

For the following activities
**The Scope of Registration appears on page 2 of this certificate**

This certificate is valid from Effective date 2024-11-21 until Expiry date 2027-11-21 and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 2021-12-10

L. Henderson

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

SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.

# Femcare Ltd.

## MDSAP (ISO 13485:2016)

Issue 2

The design, manufacture, and distribution of: Sterile implantable Tubal Ligation Clip for Female Sterilization Sterile single use Applicators for use with Tubal Ligation Clip Sterile single use Tubal Ligation Clip System (Tubal Ligation Clip and Applicator Kits) Sterile hormone replacement therapy procedure trays Sterile trocar cannula obturators for hormone replacement therapy Sterile femoral canal sponge Sterile suprapubic catheter introducer and kits Sterile replacement cannula seals Non sterile non scalpel vasectomy kits, clamps and forceps.
The design, manufacture, distribution and servicing of non-sterile reusable Applicators for use with Tubal Ligation Clip. Distribution of non-active medical devices and active medical devices (non-implantable) In the areas of gynaecological, urological, orthopaedic and general surgical procedures.

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

**Femcare Ltd**
32, Premier Way
Romsey
SO51 9DQ
United Kingdom- UK

22/02/2024

**Confirmation Letter Reference: CLNB1639 GBPC 05202**

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

**Femcare Ltd**
32, Premier Way
Romsey
SO51 9DQ
United Kingdom- UK
SRN: GB-MF-000014265

**Authorized representative:**
Utah Medical Products Ltd
Athlone Business & Technology Park, Athlone
County Westmeath
N37 XK74
Republic of Ireland
SRN: IE-AR-000007769

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15 March 2023, this letter also confirms that:

- the manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- the certificates expired after 26 May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,

Pp[Sean Kelly]
Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone : +41 22 739 98 58

**Devices covered by this letter:**

| Device name / Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| Pack1 Blister Tray<br>50555156HRTBT | Class Is | N/A | GB19/964837;<br>NB1639 |
| SterishotII Filshie standard/Mini Applicator.<br>5055515-60076<br><br>Trocar, Cannula and Obturator<br>5055515-60024<br><br>Fempac - Small / Large<br>5055515-60022<br><br>12/16 Fr - Add-a-Cath Supra-Pubic Catheter Introducer<br>5055515-60189 | Class IIa | N/A | GB19/964837;<br>NB1639 |
| Filshie Clip - Multiple packages<br>5055515-60059 | Class III | N/A | GB19/964837;<br>NB1639 |



**Confirmation Letter Revision History**

| Date | NB internal reference traceable to each version of the letter | Action |
|---|---|---|
| 16/02/2024 | Version 1 | Initial issue |

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