

The management system of

Femcare-Nikomed Ltd

Stuart Court, Spursholt Place, Salisbury Road,
Romsey, Hampshire, SO51 6DJ, UK



has been assessed and certified as meeting the requirements of

ISO 13485:2003

For the following activities

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

Effective Date 22 July 2011 Expiry Date 23 November 2012

Re certification audit due before 21 November 2012

Valid subject to satisfactory surveillance audits.

Issue 12. Certified since 07 March 2004

Authorised by

Jan Saunders – Business Manager

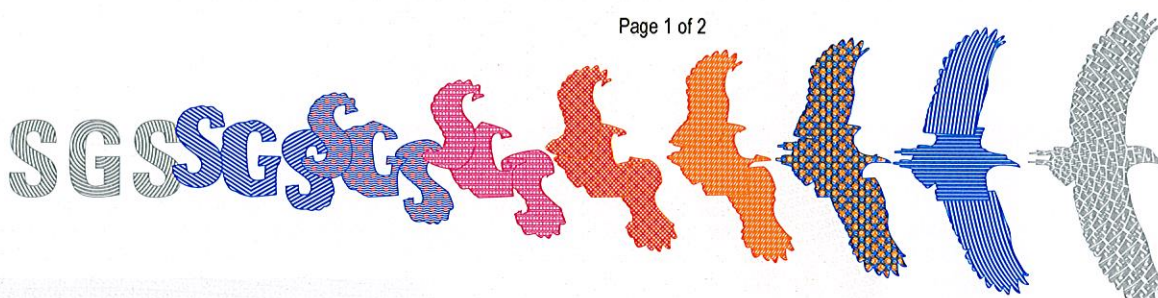


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CMDCAS recognised registrar



SGS 13485 CMDCAS 0311 M2

Page 1 of 2



Femcare-Nikomed Ltd

ISO 13485:2003



Issue 12

Detailed scope

The design and development, manufacture of:

Sterile implantable clips for female sterilisation

**Sterile single use and non sterile reusable female sterilisation clip
applicators and clip applicator kits**

Sterile single use and non sterile reusable trocar cannula

Sterile replacement cannula seals

**Sterile hormone replacement trays and sterile trocar cannula
obturators for hormone replacement therapy**

Sterile femoral sponge

Sterile suprapubic catheter introducer and kits

Sterile universal camera sleeves

**For the areas of obstetrics, gynaecology, urology and general
surgical procedures,**

Sterile Single use surgical laser fibres.

