

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.

This certificate is valid from 22 July 2011 until 21 November 2012 and
remains valid subject to satisfactory surveillance audits.
Re certification audit due before 21 November 2012
Issue 17. Certified since 23 August 1996

Authorised by



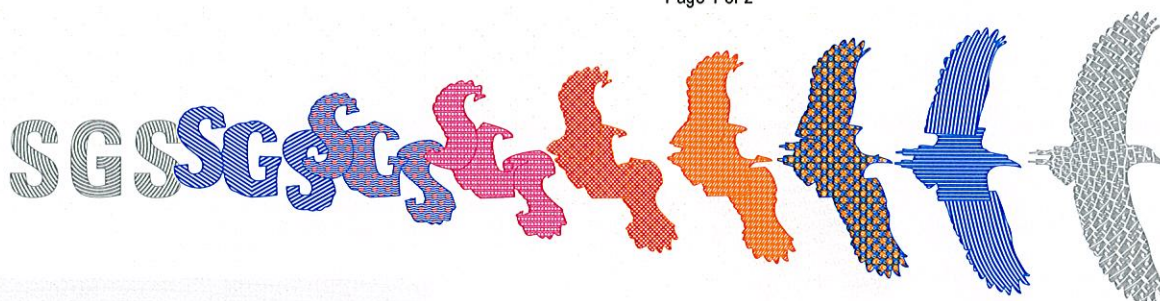
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SGS 13485-2 0311 M2

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Femcare-Nikomed Ltd

ISO 13485:2003



Issue 17

Detailed scope

Design, manufacture, servicing and distribution of:

Sterile implantable clips for female sterilisation

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

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

**Devices for gynaecological, urological, orthopaedic and general
surgical procedures,**

Sterile femoral sponge

Sterile suprapubic catheter introducer and kits

Sterile single use and non sterile reusable trocar cannula

Sterile replacement cannula seals

Sterile universal camera sleeves

Non sterile non scalpel vasectomy kit

Distribution of medical and surgical products,

Sterile Single use surgical laser fibres.



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