

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

### Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

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

This certificate is valid from 22 July 2011 until 21 November 2014 and  
remains valid subject to satisfactory surveillance audits.

Re certification audit due before 21 November 2012

Issue 18. Certified since 23 August 1996

Certification is based on reports numbered GB/PC 05202

Authorised by

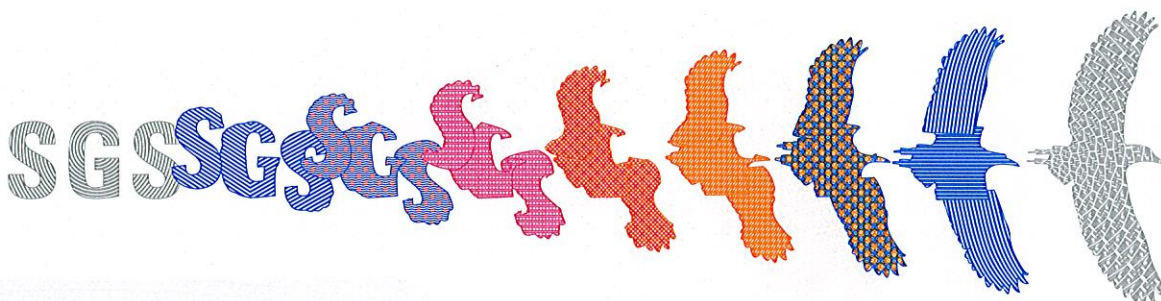


### SGS United Kingdom Ltd, Notified Body 0120

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SGS CE 01 0311 M2

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# **Femcare-Nikomed Ltd**

## **Directive 93/42/EEC**

on medical devices, Annex II (excluding section 4)

Issue 18

Detailed scope

**Sterile Filshie Sterishot system and single use disposable applicator**

**Sterile Filshie Clips**

**Sterile hormone replacement trays**

**Sterile trocar cannula obturators for hormone replacement therapy**

**Fempac sterile femoral sponge**

**Add-a-Cath sterile suprapubic catheter introducer and Add-A-Cath kits**

**Sterile single use and non sterile reusable trocar cannula**

**Sterile replacement cannula seals**

**Sterile universal camera sleeves**

**Sterile Single use surgical laser fibres.**

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.