EC Certificate Full Quality Assurance System: GB96/7942.00

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
SGS United Kingdom Ltd Systems & Services Certification
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 01 0311 M2

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.