EC Certificate Full Quality Assurance System: Certificate BE99/50313

The management system of

Gynétics Medical Products N.V.

Rembert Dodoensstraat 51
3920 Lommel, Belgium

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices,
Annex II (excluding Section 4), Annex V (sterility aspects only) and Annex V

For the following products

Annex II (excluding Section 4) :
Intra-uterine devices containing copper, Follicle aspiration needles, Endometrial suction curette (curettage/sampling). Embryo and oocytes pipettes for transfer and manipulation.

Annex V (sterility aspects only) :
Sterile disposable gynaecological sampling devices, non-surgically invasive devices for assisted human reproduction.
sterile GIS catheter: gel installation sonohysterography.
sterile Q-tip: urethral mobility tester.

Annex V:
Medium and medium sets for semen separation.

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.
For placing on the market of Class IIb or Class III devices covered by this certificate, an EC Type Examination Certificate according to Annex III is required.

This certificate is valid from 31/01/2011 until 30/01/2014 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before November 2013.
Issue 12. Certified since 30 January 1999.

Certification is based on reports numbered AND/BE 09307

Authorised by

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