EC Design Examination Certificate: Certificate BE11/23574301

Gynétics Medical Products N.V.

Rembert Dodoensstraat 51
3920 Lommel, Belgium

Device Identification:
Cu 250, Cu 375 and SOF-T Cu 375 Intra Uterine Devices

Intended Purpose of Device:
Female Contraception

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices Annex II, section 4

It is certified that the manufacturer's design dossier (and product, where applicable) for the above device has been examined and, based on the evidence submitted, it is considered that the device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjunction with a certificate covering the full quality assurance system to Annex II, which must be subject to satisfactory surveillance audits.

This certificate is valid from 4 April 2012 until 10 February 2016.
Issue 2.

Certification is based on report number(s) AND/BE 201147 dated 25/01/2011.

Addenda to that report have been issued on the following dates:

Addendum Date	Reason for Addendum
26 March 2012	Change in cleanroom facilities.

Authorised by

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