EC Design Examination Certificate: Certificate BE07/71393

Contrel Europe N.V.

Incubation and Innovation Center University of Ghent
Technology Park 3
9052 Zwijnaarde, Belgium

Device Identification:
GyneFix™ 330, GyneFix™ 200

Intended Purpose of Device:
Intrauterine Contraceptive Device

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 10 April 2011 until 9 April 2016.
Issue 4.

Certification is based on report number(s)AND/BE 07/1393.MD dated 28 March 2011.

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

Addendum Date	Reason for Addendum
11 December 2007	Renewal and addition of GyneFix™ 200
30 September 2010	Addition of Mona Lisa as a sub-contract manufacturer

Authorised by

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