EC Certificate Full Quality Assurance System: Certificate BE19/819943791

The management system of

Contrel Europe N.V.

Technology Park 82
9052 Zwijnaarde, Belgium

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 June 2020 until 24 May 2022
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 15 February 1996
and first certified by SGS Belgium NV since 16 December 2019

This is a multi-site certification.
Additional site details are listed on subsequent pages

Certification is based on reports numbered BE/AND 05343

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
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Contrel Europe N.V.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 3

Detailed scope

Sterile Intrauterine Contraceptive Devices:
- GyneFix® 200, GyneFix® 330, GyneFix®330L, GyneFix®10
- GyneFix® -CS200, GyneFix® -CS330, GyneFix® - CS330L
- GYN-CS®3, GYN-CS®5, GYN-CS®10
- GyMina®3, GyMina®5, GyMina®10,
- ReLARC® 200, ReLARC® 330, ReLARC® 330L,
- GynNext® 3, GynNext® 5, GynNext® 10,
Purpose of device: reversible long-term female contraception

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facilities

Franklin Rooseveltlaan 43-44 bus 2,
9000 Gent, Belgium