EC Certificate Full Quality Assurance System: Certificate BE10/23574093



The management system of

F Care Systems NV

Oosterveldlaan 99 2610 Wilrijk, 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 04/08/2015 until 27/03/2020 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 03/06/2010.

Re certification audit due before 27/02/2018.

Certification is based on reports numbered BE/AMD 06/1121.QMD.

Authorised by

Pieter Weterings Certification Manager

SGS Belgium NV, Notified Body 1639

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F Care Systems NV Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 4

Detailed scope:

EVRF: thermocoagulator using radiofrequency ablation intended for treatment of varicose veins, spider veins and hemorrhoids, including treatment of the great saphenous vein (vena saphena magna) and small saphenous vein (vena saphena parva).

DermaPerfect: thermocoagulator using radiofrequency ablation intended for treatment of telangiectasias and varicose veins.

Viridex RF: thermocoagulator using radiofrequency ablation intended for treatment of telangiectasias and varicose veins.

TC 3000: thermocoagulator using radiofrequency ablation intended for treatment of varicose veins.

VeinXpert: thermocoagulator using radiofrequency ablation intended for treatment of varicose veins.

Sterile invasive radiofrequency thermocoagulation probes to treat varicose veins and spider veins, as accessory for thermocoagulator EVRF.



