

Certificate

Full Quality Assurance System Approval
Annex II excluding (4) of the Directive on Medical Devices

ECM, Bismarckstr. 106, 52066 Aachen, notified to EC under 0481 hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of annex II excluding (4) of the Directive 93/42/EEC.



This certificate is issued on behalf of:

Manufacturer

Conic Vascular Technology S.A.
Via Carlo Maderno, 23, CH-6901 Lugano, Switzerland

ECM certifies that the full quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex II excluding (4) of the Directive 93/42/EEC on medical devices.

This Certificate is only valid for the products mentioned above. Special terms of validity are described in annex I to this certificate.

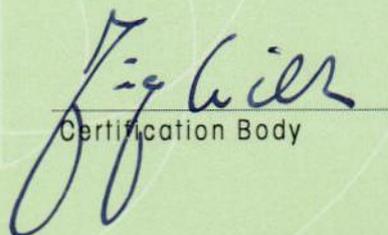
Any substantial changes of the quality assurance system or the listed products which might affect conformity to annex II of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

Report Number
418-14-925

Registered under
Z/14/03463E

Valid until
November 2nd, 2019

Aachen, November 11th, 2014


Certification Body



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-926.94.08



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Annex I of Certificate Z/14/03463E
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This certificate is valid for the hereafter following devices:

| Name of product category | Name of individual type | Nomenclature code |
|--------------------------|---|-------------------|
| Single use devices | Catheters, Vascular, Angioplasty, Balloon; Coronary Perfusion | 17-521 |

Special terms of validity:

None.