

# 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 undermentioned 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.

The approved quality assurance system is subject to periodic surveillance as defined by annex II excluding (4), section 5.

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.

**Audit Report Number**

**418-19-924**

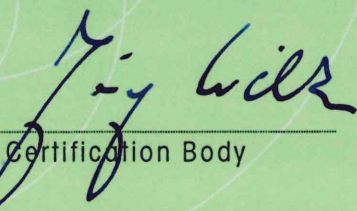
**Registered under**

**Z/19/04624E**

**Valid until**

**June 30<sup>th</sup>, 2021**

Valid as of: November 3<sup>rd</sup>, 2019

  
Certification Body



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-240.10.12

## Annex I of Certificate Z/19/04624E

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Zertifizierungsgesellschaft für  
Medizinprodukte in Europa mbH

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.