

Certificate

EC Design Examination
Annex II.4 of the Directive on Medical Devices

ECM, Bismarckstr. 106, 52066 Aachen, notified to EC under 0481 hereby declares that a design examination has been carried out on the device(s) listed in annex I to this certificate following the requirements of annex II.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 design of the device(s) listed in annex I to this certificate conforms with the requirements of annex II.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.

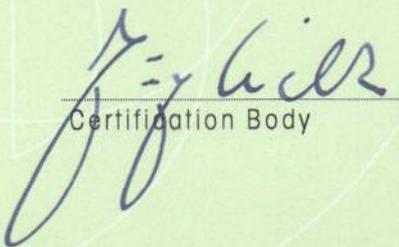
Any substantial changes of the examined product design or changes in the manufacturing process which might affect conformity to the essential requirements of the Directive 93/42/EEC or with the conditions prescribed for use of the product have to be notified to ECM and are subject to a separate approval.

Report Number
418-16F7AA

Registered under
Z/14/03464E

Valid until
November 2nd, 2019

Aachen, November 11th, 2014


Certification Body



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZE-985.94.07



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

Annex I of Certificate Z/14/03464E

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Zertifizierungsgesellschaft für
Medizinprodukte in Europa mbH

This certificate is valid for the hereafter following devices:

Name of product

category: single use devices

Nomenclature

code¹: 17-521

Name of

individual type:

Catheters, Vascular, Angioplasty, Balloon; Coronary
Perfusion

CV-150-10, CV-150-15, CV-150-20,
CV-200-10, CV-200-15, CV-200-20, CV-200-25,
CV-225-10, CV-225-15, CV-225-20, CV-225-25,
CV-225-30, CV-225-35, CV-225-40,
CV-250-10, CV-250-15, CV-250-20, CV-250-25,
CV-250-30, CV-250-35, CV-250-40,
CV-275-10, CV-275-15, CV-275-20, CV-275-25,
CV-275-30, CV-275-35, CV-275-40,
CV-300-10, CV-300-15, CV-300-20, CV-300-25,
CV-300-30, CV-300-35, CV-300-40,
CV-325-10, CV-325-15, CV-325-20, CV-325-25,
CV-325-30, CV-325-35, CV-325-40,
CV-350-10, CV-350-15, CV-350-20, CV-350-25,
CV-350-30, CV-350-35, CV-350-40,
CV-400-10, CV-400-15, CV-400-20, CV-400-25,
CV-400-30, CV-400-35, CV-400-40,
CV-450-20, CV-450-25, CV-450-30, CV-450-35,
CV-450-40

C1-150/125X15, C1-200/175X15, C1-225/200X15,
C1-250/225X15, C1-275/250X15, C1-300/275X15,
C1-325/300X15, C1-350/325X15, C1-400/375X15,
C1-150/125X20, C1-200/175X20, C1-225/200X20,
C1-250/225X20, C1-275/250X20, C1-300/275X20,
C1-325/300X20, C1-350/325X20, C1-400/375X20,
C1-200/150X25, C1-225/175X25, C1-250/200X25,
C1-275/225X25, C1-300/250X25, C1-325/275X25,
C1-350/300X25, C1-400/350X25, C1-450/400X25,
C1-225/175X30, C1-250/200X30, C1-275/225X30,
C1-300/250X30, C1-325/275X30, C1-350/300X30,
C1-400/350X30, C1-450/400X30,
C1-225/175X35, C1-250/200X35, C1-275/225X35,
C1-300/250X35, C1-325/275X35, C1-350/300X35,
C1-400/350X35, C1-450/400X35,
C1-225/175X40, C1-250/200X40, C1-275/225X40,
C1-300/250X40, C1-325/275X40, C1-350/300X40,
C1-400/350X40, C1-450/400X40

Special terms of validity: None.

¹ UMDNS Code ist optional