

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

418-017679

Registered under

Z/17/04044E

Valid until

April 2nd, 2022

Aachen, April 3rd, 2017


Certification Body



Annex I of Certificate Z/17/04044E

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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

NC-150-8, NC-150-10, NC-150-12, NC-150-15, NC-150-20,
NC-200-8, NC-200-10, NC-200-12, NC-200-15, NC-200-20, NC-200-25,
NC-225-8, NC-225-10, NC-225-12, NC-225-15, NC-225-20, NC-225-25,
NC-225-30,
NC-250-8, NC-250-10, NC-250-12, NC-250-15, NC-250-20, NC-250-25,
NC-250-30,
NC-275-8, NC-275-10, NC-275-12, NC-275-15, NC-275-20, NC-275-25,
NC-275-30,
NC-300-8, NC-300-10, NC-300-12, NC-300-15, NC-300-20, NC-300-25,
NC-300-30,
NC-325-8, NC-325-10, NC-325-12, NC-325-15, NC-325-20, NC-325-25,
NC-325-30,
NC-350-8, NC-350-10, NC-350-12, NC-350-15, NC-350-20, NC-350-25,
NC-350-30,
NC-375-8, NC-375-10, NC-375-12, NC-375-15, NC-375-20, NC-375-25,
NC-375-30,
NC-400-8, NC-400-10, NC-400-12, NC-400-15, NC-400-20, NC-400-25,
NC-400-30,
NC-450-8, NC-450-10, NC-450-12, NC-450-15, NC-450-20,
NC-500-8, NC-500-10, NC-500-12, NC-500-15, NC-500-20

Special terms of validity:

None.

¹⁾ UMDNS Code ist optional