

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

Acrostak (Schweiz) AG

Stegackerstrasse 14, 8409 Winterthur, 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

394-16B784

394-1632F6

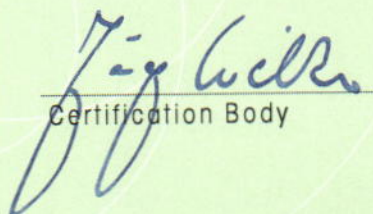
Registered under

Z/13/03146

Valid until

October 20th, 2018

Aachen, October 20th, 2013


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/13/03146

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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 ¹
single use devices	Catheters, Vascular, Angioplasty, Balloon, Coronary Perfusion	17-521
	ACROSS HP 150150350, 150200350, 200150350, 200200350 250150350, 250200350, 300150350, 300200350 250100480, 300100480, 350100480	
	ACROSS CTO 110100480, 110150480, 110200480 150100480, 150150480, 150200480 200100480, 200150480, 200200480	
	ACROSS CTO OTW 110100481; 110150481; 110200481	
	ACROSS CTO flexy 110100482; 110150482; 110200482	
	GRIP 250080340; 250120340; 250160340 300080340; 300120340; 300160340 350080340; 350120340; 350160340 400080340; 400120340; 400160340	
	GRIP TT 250080660; 250120660; 250160660 300080660; 300120660; 300160660 350080660; 350120660; 350160660 400080660; 400120660; 400160660	

Special terms of validity:

None.

¹ UMDNS Code ist optional