



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

ACCURA Medizintechnik GmbH

Max-Planck-Str. 33
61184 Karben
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Catheter, Guidewires, Angiography, Valves, Manifold, Lines, Infusion Controller, Vascular Stent, Stents according annex:

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	069418 MR2
Certificate unique ID	170654494
Effective date	2017-01-20
Expiry date	2022-01-19
Frankfurt am Main	2017-01-19

DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



Annex to certificate
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Device family	Device	Class
Catheter	UNBLOCKER Aspirations Catheter	III
	POSITOON PTCA-Balloon Catheter	III
	PERSOON PTA Balloon Catheter	Ila
Guidewire	Guidewire	Ila
	Torquer for Guidewire	Is
	Introducer-Set	Ila
	PTCA Guidewire	III
Angiography	Control Syringe	Ila
	Balloon Inflation Device	Ila
Valves	Push-Click Y Connector Kit	Ila
	Y Connector Pack	Ila
Manifold	High Pressure Manifold	Ila
	High Pressure Stopcock	Ila
Lines	High Pressure Line	Is
Infusion Controller	Infusion Controller	Ila
Stent, Vascular	FINEBENT Peripheral Vascular Self-Expanding Stent System	Ilb
Stent	CARENT Cobalt Chromium Stent	III
	DECENT Paclitaxel-Eluting Coronary Stent System	III
	DECENT S Sirolimus-Eluting Coronary Stent System	III