



# 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, 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	170728726
Effective date	2018-11-20
Expiry date	2022-01-19
Frankfurt am Main	2018-11-20

### DQS Medizinprodukte GmbH

Sigrid Uhlemann  
Managing Director

Dr. Thomas Feldmann  
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,  
Tel. +49 (0) 69 95427-300, [medical.devices@dqs-med.de](mailto:medical.devices@dqs-med.de)

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**  
**Certificate registration No.: 069418 MR2**  
**Certificate unique ID: 170728726**  
**Effective date: 2018-11-20**

## **ACCURA Medizintechnik GmbH**

Max-Planck-Str. 33  
61184 Karben  
Germany

<b>Device family</b>	<b>Device</b>	<b>Class</b>
Catheter	PERSOON PTA Balloon Catheter	Ila
Guidewire	Guidewire	Ila
	Torquer for Guidewire	Is
	Introducer-Set	Ila
	PTCA Guidewire	III
Angiography	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
Stent, Vascular	FINEBENT Peripheral Vascular Self-Expanding Stent System	IIb
Stent	DECENT S Sirolimus-Eluting Coronary Stent System	III