



# EC-CERTIFICATE

(Full quality assurance system)

## DQS Medizinprodukte GmbH

hereby certifies that the company

**Summit Doppler Systems, Inc.**  
**SummitDoppler** 4680 Table Mountain Drive #150  
Golden, CO 80403  
United States of America

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

An audit, documented in a report, performed by DQS, has verified that this quality assurance system fulfils the requirements of

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

with respect to the following medical devices:

Design, Manufacture, Distribution and Service of Doppler Ultrasound Product used in Obstetrical & Vasular Applications as listed in the annex

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body 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. In case of class Is devices the certificate is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. In case of class Im devices the certificate is restricted to the aspects of manufacture concerned with the conformity of the products with metrological requirements.

Certificate registration No.	334547 MR2
Certificate unique ID	170526106
Effective date	2011-12-31
Expiry date	2016-12-30
Frankfurt am Main	2011-12-09

Frank Graichen  
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Head of Certification Body

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



**Annex to Certificate**  
**Certificate registration No.: 334547 MR2**  
**Certificate unique ID: 170526106**  
**Effective date: 2011-12-31**

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<b>Device Group</b>	<b>Product</b>	<b>Class</b>
LifeDop Family	L150	Ila
	L150A	Ila
	L150R	Ila
	L250	Ila
	L250R	Ila
	L250AR	Ila
	L250ABI	Ila
	L300ABI	Ila
	L350R	Ila
	CT150	Ila
	CT150R	Ila
	CT250	Ila
	CT250R	Ila
	ED250	Ila
	Vista Family	Vista AVS
Vista ABI		Ila
Vantage Family	VanMax	Ila
	VanABI	Ila