



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

Balt USA, LLC.

29 Parker
Irvine, CA 92618
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.

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:

Catheters, Guidewires, Embolization Devices, Stents, Thrombo-embolectomy Devices, related accessories and SQUID – Liquid Embolic Agent as listed in the 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.	496217 MR2
Certificate unique ID	170730668
Effective date	2018-11-23
Expiry date	2023-11-22
Frankfurt am Main	2018-11-23

DQS Medizinprodukte GmbH

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Dr. Thomas Feldmann
Head of Certification Body

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	
Catheters	SONIC - Selective and Hyperselective Catheters	III	
	VASCO+ - Selective and Hyperselective Catheters	III	
	BALTACCI - Selective and Hyperselective Catheters	III	
	MAGIC - Selective and Hyperselective Catheters	III	
	CøFLC / øFTLC - Angiographic Catheters	III	
	CORAIL+ and FARGO - Guiding Catheters	III	
	ECLIPSE – COPERNIC – Temporary Occlusion Catheters	III	
	ECLIPSE2L – COPERNIC2L – Temporary Occlusion Catheters	III	
	MAGIC/BALTACCI with balloon – Temporary Occlusion Catheters	III	
	MAGIC/BALTACCI for detachable balloons – Catheters for detachable balloons	III	
	CRISTAL BALLOON – Angioplasty Catheters	III	
	Ballast 088 Long Sheath	III	
	Guidewires	HYBRID	III
	Embolization Devices	GOLDBALLOON	III
MDS - Mechanical Detachment System		III	
TANTALE		III	
TUNGSTENE		III	
Spirales (SPI), Flow-Coils (SPIF), CIRRUS (FIB)		III	
Barricade Coil System		III	
OPTIMA Coil System		III	
Stents	SILK+ - Intracranial self expandable stent	III	
	Silk Vista Baby	III	
	LEO+ / LEO+ Baby - Intracranial self expandable stent	III	
Thrombo-embolectomy Devices	CATCH+ & CATCHView	III	
Accessories	Detachment Cable Set	Is	
	Handheld Detachment Cable Set	Is	
	IVA	Ila	
	Connections (ANRYV, RYVA, RYVA LUER)	Ila	
	XCEL Detachment Controller	Ila	



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Device family	Device	Class
SQUID – Liquid Embolic Agent Family	SQUID18	III
	SQUID18LD	III
	SQUID12	III
	SQUID12LD	III
	SQUID PERI 18	IIb
	SQUID PERI 18 LD	IIb
	SQUID PERI 12	IIb
	SQUID PERI 12 LD	IIb
	SQUID34	III
	SQUID34LD	III
	SQUID PERI 34	IIb
	SQUID PERI 34 LD	IIb