

EC-Certificate

(full quality assurance system)
according to annex II (excluding section 4) of
Medical Devices Directive 93/42/EEC

It is herewith confirmed by

**EUROCAT Institute for
Certification and Testing**

Quarat[®] Center * Wittichstraße 2
64295 Darmstadt * Germany

in its function as Notified Body (0535), that the manufacturer:



eucatech AG

Gottlieb-Daimler-Str. 2
79618 Rheinfelden, Germany

concerning the medical devices

**Balloon Catheters, Stents, Stent Systems,
Multipurpose Catheters,
Drug Eluting Stents, Drug Eluting
Stent Systems**

(products/variants specified in enclosure)
fulfils the requirements according to Annex II (excluding
section 4) Medical Devices Directive 93/42/EEC. The
manufacturer has established a quality assurance system for
the design, production and final inspection of specified
devices.

For the placing on the market of class III products an Annex
II section 4 certificate is required.

The appendix is part of this certificate and contains 1 page.

Report No.: BQM10350HU01

Certificate No.: CE 576299 (ZQ090011-II)

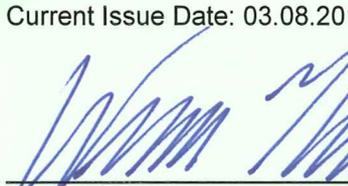
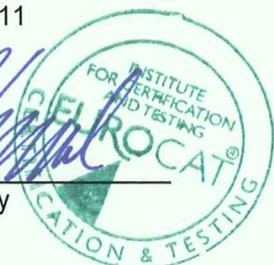


Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten www.zlg.de
ZLG-BS-248.10.04

First Issue Date:
01 January 2009.

Based on periodical surveillance
this certificate is valid until
15.12.2015.

Current Issue Date: 03.08.2011


Certification Body 

Appendix of EC-Certificate

(full quality assurance system)

according to annex II (excluding section 4) of Medical Devices Directive 93/42/EEC

Certificate No.: CE 576299 (ZQ090011-II)

Medical devices of the manufacturer:



eucatech AG

Gottlieb-Daimler-Str. 2

79618 Rheinfelden, Germany

Peripheral Balloon Catheter "euca PW"		Class IIa	
Name of product	Nom. balloon diameter	Balloon length	Shaft length
euca PW D.DD x LL - SSS	D.DD = 4.00 – 12.00mm	LL = 10 – 80mm	SSS = 50 – 150cm
euca PW ^{SV} D.dd x LL-SSS	D.DD = 2.00 – 5.00mm	LL = 10 – 150mm	SSS = 50 – 150cm

Peripheral Stainless Steel Stent System "euca PWS"		Class IIb	
Name of product	Nom. stent diameter	Stent length	Shaft length
euca PWS DD / LL-SSS	DD = 4mm – 12mm	LL = 18mm – 78mm	SSS = 50 – 150cm

Self expandable Nitinol Stent System "RESISTANT"		Class IIb	
Name of product	Nom. stent OD	Stent length	Shaft length
RESISTANT DD / LLL - SSS	D.DD = 4 – 12mm	LLL = 20 – 100mm	SSS = 85cm - 135cm



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten www.zlg.de
ZLG-BS-248.10.04

Darmstadt, 03 August 2011

EUROCAT Institute for Certification and Testing GmbH, 64295 Darmstadt, Germany,

