



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



Product Service

# EC Certificate

EC Design-Examination Certificate  
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)  
(Devices in Class III)

**No. G7 019742 0091 Rev. 01**

**Manufacturer:** **VascoMed GmbH**  
Hertzallee 1  
79589 Binzen  
GERMANY

**Product:** **Cardiac Ablation Catheters**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:G7\\_019742\\_0091\\_Rev.01](http://www.tuvsud.com/ps-cert?q=cert:G7_019742_0091_Rev.01)

**Report no.:** 713201688

**Valid from:** 2021-02-23

**Valid until:** 2024-05-26

**Date,** 2021-02-23

Christoph Dicks  
Head of Certification/Notified Body



# EC Certificate

EC Design-Examination Certificate  
 Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)  
 (Devices in Class III)

**No. G7 019742 0091 Rev. 01**

**Model(s):** **AICath, AICath Flux eXtra, AICath Flutter, AcQBlate Ablation Catheter, AcQBlate EvenTemp Ablation Catheter**

**Parameter:**

Product group	Model name	Model number
<b>AICath Flux G eXtra</b>	AICath Flux Red G eXtra	376379
	AICath Flux Blue G eXtra	376388
	AICath Flux Green G eXtra	376384
	AICath Flux Black G eXtra	376390
	AICath Flux Cyan G eXtra	376386
<b>AICath Flutter</b>	AICath Flutter Flux Black G eXtra	380783
	AICath Flutter Black LT G	368997
<b>AICath TC LT G FullCircle</b>	AICath Red TC LT G FullCircle	364539
	AICath Blue TC LT G FullCircle	364527
	AICath Green TC LT G FullCircle	364535
	AICath Black TC LT G FullCircle	364524
	AICath Cyan TC LT G FullCircle	364531
<b>AICath TC LT FullCircle</b>	AICath Red TC LT FullCircle	364538
	AICath Blue TC LT FullCircle	364526
	AICath Green TC LT FullCircle	364534
	AICath Black TC LT FullCircle	364523
	AICath Cyan TC LT FullCircle	364530
<b>AICath TC G FullCircle</b>	AICath Red TC G FullCircle	364537
	AICath Blue TC G FullCircle	364525
	AICath Green TC G FullCircle	364533
	AICath Black TC G FullCircle	364522
	AICath Cyan TC G FullCircle	364529
<b>AICath TC FullCircle</b>	AICath Red TC FullCircle	364536
	AICath Blue TC FullCircle	359038
	AICath Green TC FullCircle	364532
	AICath Black TC FullCircle	359037
	AICath Cyan TC FullCircle	364528



# EC Certificate

EC Design-Examination Certificate  
 Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)  
 (Devices in Class III)

**No. G7 019742 0091 Rev. 01**

<b>AICath Flux eXtra</b>	AICath Flux Red eXtra	376383
	AICath Flux Blue eXtra	376389
	AICath Flux Green eXtra	376385
	AICath Flux Black eXtra	376391
	AICath Flux Cyan eXtra	376387
<b>AcQBlate EvenTemp Ablation Catheter</b>	AcQBlate Gold EvenTemp Ablation Catheter Red	460599
	AcQBlate Gold EvenTemp Ablation Catheter Blue	460600
	AcQBlate Gold EvenTemp Ablation Catheter Green	460601
	AcQBlate Gold EvenTemp Ablation Catheter Black	460602
	AcQBlate Gold EvenTemp Ablation Catheter Cyan	460603
	AcQBlate Gold EvenTemp Flutter Ablation Catheter Black	460604
<b>AcQBlate Ablation Catheter</b>	AcQBlate Gold 8mm Flutter Ablation Catheter Black	460605
	AcQBlate Gold 8mm Ablation Catheter Red	460583
	AcQBlate Gold 8mm Ablation Catheter Blue	460584
	AcQBlate Gold 8mm Ablation Catheter Green	460585
	AcQBlate Gold 8mm Ablation Catheter Black	460586
	AcQBlate Gold 8mm Ablation Catheter Cyan	460587
	AcQBlate 8mm Ablation Catheter Red	460578
	AcQBlate 8mm Ablation Catheter Blue	460579
	AcQBlate 8mm Ablation Catheter Green	460580
	AcQBlate 8mm Ablation Catheter Black	460581
	AcQBlate 8mm Ablation Catheter Cyan	460582
	AcQBlate Gold 4mm Ablation Catheter Red	460593
	AcQBlate Gold 4mm Ablation Catheter Blue	460594
	AcQBlate Gold 4mm Ablation Catheter Green	460595
	AcQBlate Gold 4mm Ablation Catheter Black	460596
	AcQBlate Gold 4mm Ablation Catheter Cyan	460597
	AcQBlate 4mm Ablation Catheter Red	460588
	AcQBlate 4mm Ablation Catheter Blue	460589
	AcQBlate 4mm Ablation Catheter Green	460590
	AcQBlate 4mm Ablation Catheter Black	460591
AcQBlate 4mm Ablation Catheter Cyan	460592	



# EC Certificate

EC Design-Examination Certificate  
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)  
(Devices in Class III)

**No. G7 019742 0091 Rev. 01**

## Explanation of the abbreviations:

FullCircle = the distal tip section forms a closed circle under full deflection

Flux = irrigated catheter

TC = thermocouple

G = Tip- and ring electrodes are made of Gold; when G is not indicated on the product, the tip and ring electrodes are manufactured of Platinum / Iridium alloy

Length of tip electrode:

non-irrigated configurations:

LT = Long Tip electrode, length of the tip electrode is 8 mm when LT is not indicated on the product  
the tip electrode length is 4 mm

irrigated configurations:

eXtra = the length of the tip electrode is 3.5 mm and the electrode has 12 irrigation ports