



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

Report no.: 713201688

Valid from: 2021-02-23

Valid until: 2024-05-26

Date, 2021-02-23

Christoph Dicks
Head of Certification/Notified Body



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Model(s):

**AlCath, AlCath Flux eXtra, AlCath Flutter,
AcQBlate Ablation Catheter, AcQBlate
EvenTemp Ablation Catheter**

Parameter:

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



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AlCath Flux eXtra	AlCath Flux Red eXtra	376383
	AlCath Flux Blue eXtra	376389
	AlCath Flux Green eXtra	376385
	AlCath Flux Black eXtra	376391
	AlCath Flux Cyan eXtra	376387
AcQBlate EvenTemp Ablation Catheter	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
AcQBlate Ablation Catheter	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



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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