



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 0081 Rev. 03

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

Product: **Cardiac Diagnostic 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_0081_Rev.03

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 0081 Rev. 03

Model(s): **MultiCath**
Catheters for electrophysiological diagnostics
AcQRate Dx Fixed Curve Catheter

Parameters:

Product group	Model name	Model number
MultiCath 4 F	MultiCath 4J Sp ø4F 5mm	356728
	MultiCath 4J Sp ø4F 2-5-2mm	356727
MultiCath 5 F	MultiCath 4J Sp ø5F 2mm	351170
	MultiCath 4J Sp 100cm ø5F 5 mm	356434
	MultiCath 4J Sp ø5F 2-5-2mm	351171
	MultiCath 4J Sp 100cm ø5F 2-5-2mm	356433
	MultiCath 4C ø5F 2-5-2mm	351177
	MultiCath 4HIS ø5F 5mm	359385
	MultiCath 10J Sp ø5F 2-5-2mm	359388
	MultiCath 10J Sp ø5F 2-8-2mm	359389
MultiCath 6 F	MultiCath 4J ø6F 5mm	351185
	MultiCath 4J ø6F 5mm SoftTip	351182
	MultiCath 4D ø6F 5mm	351189
	MultiCath 4C ø6F 5mm	351188
	MultiCath 4C ø6F 5mm SoftTip	351183
	MultiCath 4M ø6F 5mm	351194
	MultiCath 5J ø6F 5-5-5-280mm	369066
	MultiCath 10J ø6F 5mm	351193
	MultiCath 10J CS ø6F 2-5-2mm	351192
	MultiCath 10J CS ø6F 2-8-2mm	351191



EC Certificate

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

No. G7 019742 0081 Rev. 03

AcQRate Dx Fixed Curve Catheter	AcQRate Dx Fixed Curve Catheter 4J Sp 4F 5mm	460636
	AcQRate Dx Fixed Curve Catheter 4J Sp 4F 2-5-2mm	460637
	AcQRate Dx Fixed Curve Catheter 4J Sp 5F 2mm	460638
	AcQRate Dx Fixed Curve Catheter 4J Sp 100cm 5F 5mm	460639
	AcQRate Dx Fixed Curve Catheter 4J Sp 5F 2-5-2mm	460641
	AcQRate Dx Fixed Curve Catheter 4J Sp 100cm 5F 2-5-2mm	460640
	AcQRate Dx Fixed Curve Catheter 4C 5F 2-5-2mm	460642
	AcQRate Dx Fixed Curve Catheter 4 HIS 5F 5mm	460643
	AcQRate Dx Fixed Curve Catheter 10J Sp 5F 2-5-2mm	460651
	AcQRate Dx Fixed Curve Catheter 10J Sp 5F 2-8-2mm	460652
	AcQRate Dx Fixed Curve Catheter 4J 6F 5mm	460644
	AcQRate Dx Fixed Curve Catheter 4J 6F 5mm Soft Tip	460645
	AcQRate Dx Fixed Curve Catheter 4D 6F 5mm	460646
	AcQRate Dx Fixed Curve Catheter 4C 6F 5mm	460647
	AcQRate Dx Fixed Curve Catheter 4C 6F 5mm Soft Tip	460648
	AcQRate Dx Fixed Curve Catheter 4M 6F 5mm	460649
	AcQRate Dx Fixed Curve Catheter 5J 6F 5-5-5-280mm	460650
	AcQRate Dx Fixed Curve Catheter 10J 6F 5mm	460653
	AcQRate Dx Fixed Curve Catheter 10J CS 6F 2-5-2mm	460654
	AcQRate Dx Fixed Curve Catheter 10J CS 6F 2-8-2mm	460655

Explanation of abbreviations:

MultiCath n/c/d/s

n Number of electrodes

c Curve design (C: Courmand, D: Damato, J: Josephson, Jsp: Josephson special, M: Multipurpose, HIS: HIS)

d Diameter

s Electrode spacing (in mm)