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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 0093 Rev. 01

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_0093_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):

ViaCath, AcQRate Dx Steerable Catheter

Parameter:

Product group	Model name	Model number
ViaCath NG	ViaCath NG 4/S/5mm	351197
	ViaCath NG 4/S/10mm	351196
	ViaCath NG 10/S/2-6-2mm	351200
	ViaCath NG 10/L/2-6-2mm	358797
	ViaCath NG 10/L/2-8-2mm	370309
	ViaCath NG 10/XL/2-10-2mm	370144
ViaCath	ViaCath 20/XL/2-10-2mm	351201
AcQRate Dx Steerable Catheter	AcQRate Dx Steerable Catheter 4/S/5mm	460656
	AcQRate Dx Steerable Catheter 4/S/10mm	460657
	AcQRate Dx Steerable Catheter 10/S/2-6-2mm	460658
	AcQRate Dx Steerable Catheter 10/L/2-6-2mm	460659
	AcQRate Dx Steerable Catheter 10/L/2-8-2mm	460660
	AcQRate Dx Steerable Catheter 10/XL/2-10-2mm	460661
	AcQRate Dx Steerable Catheter 20/XL/2-8-2mm	460662

Explanation of the abbreviations:

ViaCath (NG) n / c / s

n Number of electrodes

c Curve design (S = Standard, L = Large, XL = Extra Large)

s Electrode spacing (in mm)