



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 15 11 19742 079

**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. See also notes overleaf.

**Report no.:**

713065825

**Valid from:**

2016-01-20

**Valid until:**

2021-01-19

**Date,** 2015-12-21

Hans-Heiner Junker



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**EC Certificate****EC Design-Examination Certificate**

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)  
(Devices in Class III)

**No. G7 15 11 19742 079****Model(s):**

**ViaCath**  
**(details see attachment)**

**Parameters:**

./.

**Facility(ies):**

VascoMed GmbH  
Hertzallee 1, 79589 Binzen, GERMANY

VascoMed GmbH  
Marie-Curie-Strasse 8, 79539 Lörrach, GERMANY

VascoMed GmbH  
Pasteurallee 1, 79589 Binzen, GERMANY

**Design****Facility(ies):**

VascoMed GmbH  
Hertzallee 1, 79589 Binzen, GERMANY



Product Service

**Attachment for Certificate no G7 15 11 19742 079**  
**dated 2015-12-21**

**Product:** Cardiac Diagnostic Catheters

**Test Report No.:** 71376008 / DM1008538

**Model:** ViaCath (Steerable catheters for electrophysiological diagnostics)

| Product group | Product name               |
|---------------|----------------------------|
| ViaCath NG    | ViaCath NG 4/S/5 mm        |
|               | ViaCath NG 4/S/10 mm       |
|               | ViaCath NG 8/S/5 mm        |
|               | ViaCath NG 10/S/2-6-2 mm   |
|               | ViaCath NG 10/L/2-6-2 mm   |
|               | ViaCath NG 10/L/2-8-2 mm   |
|               | ViaCath NG 10/XL/2-10-2 mm |
| ViaCath       | ViaCath 20/XL/2-8-2 mm     |

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)

Munich, CRT2, 2015-12-21

Hans-Heiner Junker  
 Certification Medical Technology



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 15 11 19742 081

### 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. See also notes overleaf.

### Report no.:

713065918

### Valid from:

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### Valid until:

2021-01-19

Date, 2015-12-21

Hans-Heiner Junker



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**EC Certificate****EC Design-Examination Certificate**

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)  
(Devices in Class III)

**No. G7 15 11 19742 081**

|                                  |                                                                                                                                                                                          |
|----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Model(s):</b>                 | <b>MultiCath</b><br><b>(details see attachment)</b>                                                                                                                                      |
| <b>Parameters:</b>               | ./.                                                                                                                                                                                      |
| <b>Facility(ies):</b>            | VascoMed GmbH<br>Hertzallee 1, 79589 Binzen, GERMANY<br><br>VascoMed GmbH<br>Marie-Curie-Strasse 8, 79539 Lörrach, GERMANY<br><br>VascoMed GmbH<br>Pasteurallee 1, 79589 Binzen, GERMANY |
| <b>Design<br/>Facility(ies):</b> | VascoMed GmbH<br>Hertzallee 1, 79589 Binzen, GERMANY                                                                                                                                     |

**Attachment for Certificate no G7 15 11 19742 081  
dated 2015-12-21**



Product Service

**Product:** Cardiac Diagnostic Catheters

**Test Report No.:** 71376014 / DM1008517

**Model:** MultiCath (Catheters for electrophysiological diagnostics)

| Product group | Product name                       |
|---------------|------------------------------------|
| MultiCath 4F  | MultiCath 4J Sp ø4F 5 mm           |
|               | MultiCath 4C ø4F 5 mm              |
|               | MultiCath 4J Sp ø4F 2-5-2 mm       |
|               | MultiCath 4C ø4F 2-5-2 mm          |
| MultiCath 5F  | MultiCath 4J Sp ø5F 2 mm           |
|               | MultiCath 10C ø5F 2 mm             |
|               | MultiCath 10J Sp ø5F 2 mm          |
|               | MultiCath 4J Sp 100cm ø5F 5 mm     |
|               | MultiCath 4J Sp ø5F 2-5-2 mm       |
|               | MultiCath 4J Sp 100cm ø5F 2-5-2 mm |
|               | MultiCath 4D St ø5F 2-5-2 mm       |
|               | MultiCath 4D La ø5F 2-5-2 mm       |
|               | MultiCath 4C ø5F 2-5-2 mm          |
|               | MultiCath 4 HIS ø5F 5 mm           |
|               | MultiCath 4M ø5F 5 mm              |
|               | MultiCath 6J Sp ø5F 2-5-2 mm       |
|               | MultiCath 10J Sp ø5F 2-5-2 mm      |
|               | MultiCath 10J Sp ø5F 2-8-2 mm      |
| MultiCath 6F  | MultiCath 2J ø6F 5 mm              |
|               | MultiCath 2D ø6F 5 mm              |
|               | MultiCath 4J ø6F 5 mm              |
|               | MultiCath 4J ø6F 5 mm Soft Tip     |
|               | MultiCath 4D ø6F 5 mm              |
|               | MultiCath 4D ø6F 5 mm Soft Tip     |
|               | MultiCath 4C ø6F 5 mm              |
|               | MultiCath 4C ø6F 5 mm Soft Tip     |
|               | MultiCath 4M ø6F 5 mm              |
|               | MultiCath 4M ø6F 5 mm Soft Tip     |
|               | MultiCath 5J ø6F 5-5-5-280 mm      |
|               | MultiCath 10J ø6F 2 mm             |
|               | MultiCath 10J ø6F 5 mm             |
|               | MultiCath 10J CS ø6F 2-5-2 mm      |
|               | MultiCath 10J CS ø6F 2-8-2 mm      |

**Attachment for Certificate no G7 15 11 19742 081  
dated 2015-12-21**



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Explanation of abbreviations:

MultiCath n/c/d/s

- n Number of electrodes
- c Curve design (C: Cournand, D: Damato, Dia: Damato large, Dst: Damato standard, J: Josephson, Jsp: Josephson special, M: Multipurpose, HIS: HIS)
- d Diameter
- s Electrode spacing (in mm)

Munich, CRT2, 2015-12-21

Hans-Heiner Junker  
Certification Medical Technology



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 15 11 19742 082

**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. See also notes overleaf.

**Report no.:**

713065913

**Valid from:**

2016-01-20

**Valid until:**

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**Date,** 2015-12-21

Hans-Heiner Junker



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**EC Certificate****EC Design-Examination Certificate**

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)  
(Devices in Class III)

**No. G7 15 11 19742 082**

**Model(s):** AICath, AICath Flux eXtra, AICath Flutter  
(details see attachment)

**Parameters:** ./.

**Facility(ies):**

VascoMed GmbH  
Hertzallee 1, 79589 Binzen, GERMANY

VascoMed GmbH  
Marie-Curie-Strasse 8, 79539 Lörrach, GERMANY

VascoMed GmbH  
Pasteurallee 1, 79589 Binzen, GERMANY

**Design Facility(ies):**

VascoMed GmbH  
Hertzallee 1, 79589 Binzen, GERMANY



**Attachment for Certificate no G7 15 11 19742 082**  
**dated 2015-12-21**

**Product:** Cardiac Ablation Catheters

**Test Report No.:** 71376016 / DM1008518, 713013687

**Model:** AICath, AICath Flux eXtra, AICath Flutter  
 (Non-irrigated and irrigated mapping and ablation catheters)

| Product group             | Product name                      |
|---------------------------|-----------------------------------|
| AICath TC LT G            | AICath Black TC LT G              |
| AICath TC G               | AICath Blue TC G                  |
|                           | AICath Black TC G                 |
| AICath TC LT FullCircle   | AICath Red TC LT FullCircle       |
|                           | AICath Blue TC LT FullCircle      |
|                           | AICath Green TC LT FullCircle     |
|                           | AICath Black TC LT FullCircle     |
|                           | AICath Cyan TC LT FullCircle      |
| AICath TC LT G FullCircle | AICath Red TC LT G FullCircle     |
|                           | AICath Blue TC LT G FullCircle    |
|                           | AICath Green TC LT G FullCircle   |
|                           | AICath Black TC LT G FullCircle   |
|                           | AICath Cyan TC LT G FullCircle    |
| AICath TC FullCircle      | AICath Red TC FullCircle          |
|                           | AICath Blue TC FullCircle         |
|                           | AICath Green TC FullCircle        |
|                           | AICath Black TC FullCircle        |
|                           | AICath Cyan TC FullCircle         |
| AICath TC G FullCircle    | AICath Red TC G FullCircle        |
|                           | AICath Blue TC G FullCircle       |
|                           | AICath Green TC G FullCircle      |
|                           | AICath Black TC G FullCircle      |
|                           | AICath Cyan TC G FullCircle       |
| AICath Flux eXtra         | AICath Flux Red eXtra             |
|                           | AICath Flux Blue eXtra            |
|                           | AICath Flux Green eXtra           |
|                           | AICath Flux Black eXtra           |
|                           | AICath Flux Cyan eXtra            |
| AICath Flux G eXtra       | AICath Flux Red G eXtra           |
|                           | AICath Flux Blue G eXtra          |
|                           | AICath Flux Green G eXtra         |
|                           | AICath Flux Black G eXtra         |
|                           | AICath Flux Cyan G eXtra          |
| AICath Flutter            | AICath Flutter Black LT G         |
|                           | AICath Flutter Flux Black G eXtra |



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**Attachment for Certificate no G7 15 11 19742 082  
dated 2015-12-21**

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

Munich, CRT2, 2015-12-21

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