



# Vascular and Cardiothoracic Surgery Solutions

Over 50 years of technical and clinical  
experience in vascular graft technology

This document is intended to provide information to an  
international audience.

Lot : 5

# Hemacarotid Patch Knitted

## Knitted Patches



### Material\*:

- Collagen-coated polyester patch
- Reverse lock-knit knitting technique
- Magnetic Resonance Safe
- Water permeability : < 5ml/cm<sup>2</sup>/min

### Hemacarotid Patch Knitted

| Dimensions    | Reference      |
|---------------|----------------|
| 6 mm x 75 mm  | HEK06/75CP (1) |
| 8 mm x 75 mm  | HEK08/75CP (1) |
| 10 mm x 75 mm | HEK10/75CP (1) |
| 12 mm x 75 mm | HEK12/75CP (1) |
| 14 mm x 75 mm | HEK14/75CP (1) |

\*Hemacarotid Patch Knitted IFU

## DECLARATION OF CONFORMITY

**MANUFACTURER :** INTERVASCULAR SAS • Z.I. Athélia 1• 13705 La Ciotat Cedex • FRANCE

**PRODUCT :** Vascular Grafts  
INTERGARD Standard

**MODEL :** INTERGARD Standard - Collagen Coated Vascular Graft and Patches

| Product Category                                   | Product Name   |
|--|--|
| Knitted Collagen Coated Vascular Grafts            | - INTERGARD Knitted<br>- HEMAGARD Knitted  |
| Knitted Ultrathin Collagen Coated Vascular Grafts  | - INTERGARD Knitted Ultrathin<br>- HEMAGARD Knitted Ultrathin  |
| Woven Collagen Coated Vascular Grafts              | - INTERGARD Woven<br>- CARDIOROOT Woven  |
| Knitted Collagen Coated Vascular Patches           | - HEMAPATCH Knitted<br>- HEMAGARD PATCH Knitted<br>- HEMACAROTID PATCH Knitted<br>- HEMAGARD CAROTID Patch Knitted |
| Knitted Ultrathin Collagen Coated Vascular Patches | - HEMACAROTID Patch Knitted Ultrathin<br>- HEMAGARD CAROTID Patch Knitted Ultrathin                                |
| Woven Collagen Coated Vascular Patches             | - HEMAPATCH Woven  |

(See Appendix 1 for product references)

**CLASSIFICATION:** Class III (MDD 93/42/EEC Annex IX, rules 8 and 17)

**CONFORMITY ASSESSMENT ROUTE:** Annex II sections 3 and 4 of the MDD

We herewith declare exclusively under sole responsibility that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Devices. In addition, we declare that the above mentioned products fulfill the applicable provisions of the Regulation (EU) No 722/2012.

All supporting documentation is retained under the premises of the manufacturer.

**NOTIFIED BODY:** TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • GERMANY  
Identification no. 0123

**EC CERTIFICATE:** EC Design-Examination Certificate No G7AO 103025 0016 Rev.01 (Annex II clause 4)  
EC Certificate - Full Quality Assurance System No G1 103025 0006 Rev. 02 (Annex II excluding 4)



**Laure Fraysse**  
Regulatory Compliance Director



**Date**  
La Ciotat, France

*Last Revision date: July 2020*

## Appendix 1

### 1. INTERGARD/HEMAGARD Knitted

The following codifications are used within this group:

- IGK (INTERGARD Knitted)
- HGK (HEMAGARD Knitted)
- RS (Radially Supported)
- AX (Axillo bifemoral)
- T (Trifurcated)
- Q (Quadrifurcated)

#### INTERGARD Knitted Straight

| Reference   | Diameter | Length | Device identifier (DI) |
|-------------|----------|--------|------------------------|
| IGK0006-20  | 6 mm     | 20 cm  | 00384401007555         |
| IGK0006-40  | 6 mm     | 40 cm  | 00384401000914         |
| IGK0006-70  | 6 mm     | 70 cm  | 00384401000365         |
| IGK0007-20  | 7 mm     | 20 cm  | 00384401007562         |
| IGK0007-40  | 7 mm     | 40 cm  | 00384401000921         |
| IGK0007-70  | 7 mm     | 70 cm  | 00384401000860         |
| IGK0008-20  | 8 mm     | 20 cm  | 00384401007586         |
| IGK0008-40  | 8 mm     | 40 cm  | 00384401000938         |
| IGK0008-70  | 8 mm     | 70 cm  | 00384401000372         |
| IGK0008-100 | 8 mm     | 100 cm | 00384401000440         |
| IGK0010-20  | 10 mm    | 20 cm  | 00384401007593         |
| IGK0010-40  | 10 mm    | 40 cm  | 00384401000389         |
| IGK0010-70  | 10 mm    | 70 cm  | 00384401001355         |
| IGK0012-20  | 12 mm    | 20 cm  | 00384401001607         |
| IGK0012-40  | 12 mm    | 40 cm  | 00384401001393         |
| IGK0014-20  | 14 mm    | 20 cm  | 00384401000945         |
| IGK0014-40  | 14 mm    | 40 cm  | 00384401000396         |
| IGK0016-20  | 16 mm    | 20 cm  | 00384401000952         |
| IGK0016-40  | 16 mm    | 40 cm  | 00384401000402         |
| IGK0018-20  | 18 mm    | 20 cm  | 00384401000969         |
| IGK0018-40  | 18 mm    | 40 cm  | 00384401000693         |
| IGK0020-20  | 20 mm    | 20 cm  | 00384401000976         |
| IGK0020-40  | 20 mm    | 40 cm  | 00384401001409         |
| IGK0022-20  | 22 mm    | 20 cm  | 00384401000983         |
| IGK0022-40  | 22 mm    | 40 cm  | 00384401000419         |
| IGK0024-20  | 24 mm    | 20 cm  | 00384401000990         |
| IGK0024-40  | 24 mm    | 40 cm  | 00384401000426         |

**INTERGARD Knitted Straight Radially Supported (RS)**

| Reference   | Diameter | Proximal/Distal length | Supported length | Total length | Device identifier (DI) |
|-------------|----------|------------------------|------------------|--------------|------------------------|
| IGK0006RS20 | 6 mm     | 35 cm/15 cm            | 20 cm            | 70 cm        | 00384401000716         |
| IGK0006RS30 | 6 mm     | 25 cm/15 cm            | 30 cm            | 70 cm        | 00384401000723         |
| IGK0008RS15 | 8 mm     | 40 cm/15 cm            | 15 cm            | 70 cm        | 00384401004028         |
| IGK0008RS20 | 8 mm     | 35 cm/15 cm            | 20 cm            | 70 cm        | 00384401000754         |
| IGK0008RS30 | 8 mm     | 25 cm/15 cm            | 30 cm            | 70 cm        | 00384401000761         |
| IGK0008RS45 | 8 mm     | 20 cm/20 cm            | 45 cm            | 85 cm        | 00384401000778         |

**INTERGARD Knitted Axillo-bifemoral**

| Reference | Diameter   | Distal length (Body/Branch) | Supported length (Body/Branch) | Total length (Body/Branch) | Device identifier (DI) |
|-----------|------------|-----------------------------|--------------------------------|----------------------------|------------------------|
| IGKAX1010 | 10 x 10 mm | N/A                         | N/A                            | 100 cm/60 cm               | 00384401001102         |

**INTERGARD Knitted Axillo-bifemoral Radially Supported (RS)**

| Reference          | Diameter      | Distal length (Body/Branch) | Supported length (Body/Branch) | Total length (Body/Branch) | Device identifier (DI) |
|--------------------|---------------|-----------------------------|--------------------------------|----------------------------|------------------------|
| IGKAX0808RS45/20   | 8 x 8 mm      | 20 cm/35 cm                 | 45 cm/20 cm                    | 85 cm/55 cm                | 00384401000709         |
| IGKAX0808RS45/30   | 8 x 8 mm      | 20 cm/25 cm                 | 45 cm/30 cm                    | 85 cm/55 cm                | 00384401000877         |
| IGKAX0808RS60/30   | 8 x 8 mm      | 20 cm/25 cm                 | 60 cm/30 cm                    | 100 cm/55 cm               | 00384401000884         |
| IGKAX100808RS35/20 | 10 x 8 x 8 mm | 25 cm/35 cm                 | 35 cm/20 cm                    | 85 cm/55 cm                | 00384401006039         |
| IGKAX080606RS35/20 | 8 x 6 x 6 mm  | 25 cm/35 cm                 | 35 cm/20 cm                    | 85 cm/55 cm                | 00384401001614         |

**INTERGARD Knitted Bifurcated**

| Reference | Diameter   | Length | Device identifier (DI) |
|-----------|------------|--------|------------------------|
| IGK1206   | 12 x 6 mm  | 50 cm  | 00384401000464         |
| IGK1407   | 14 x 7 mm  | 50 cm  | 00384401000471         |
| IGK1608   | 16 x 8 mm  | 50 cm  | 00384401000488         |
| IGK1809   | 18 x 9 mm  | 50 cm  | 00384401000495         |
| IGK2010   | 20 x 10 mm | 50 cm  | 00384401000501         |
| IGK2211   | 22 x 11 mm | 50 cm  | 00384401000518         |
| IGK2412   | 24 x 12 mm | 50 cm  | 00384401000525         |

### INTERGARD Knitted Trifurcated

| Reference   | Diameter       | Length (Body/Branches) | Device identifier (DI) |
|-------------|----------------|------------------------|------------------------|
| IGKT1407    | 14 x 7 mm      | 20 cm/35 cm            | 00384401003366         |
| IGKT1608    | 16 x 8 mm      | 20 cm/35 cm            | 00384401000600         |
| IGKT1809    | 18 x 9 mm      | 20 cm/35 cm            | 00384401000617         |
| IGKT2010    | 20 x 10 mm     | 20 cm/35 cm            | 00384401003427         |
| IGKT140707L | 14 x 7 x 7 mm  | 15 cm/35 cm/34 cm      | 00384401013945         |
| IGKT140707R | 14 x 7 x 7 mm  | 15 cm/35 cm/34 cm      | 00384401013952         |
| IGKT160808L | 16 x 8 x 8 mm  | 15 cm/35 cm/34 cm      | 00384401013969         |
| IGKT160808R | 16 x 8 x 8 mm  | 15 cm/35 cm/34 cm      | 00384401013976         |
| IGKT180908L | 18 x 9 x 8 mm  | 15 cm/35 cm/34 cm      | 00384401013983         |
| IGKT180908R | 18 x 9 x 8 mm  | 15 cm/35 cm/34 cm      | 00384401013990         |
| IGKT201009L | 20 x 10 x 9 mm | 15 cm/35 cm/34 cm      | 00384401014003         |
| IGKT201009R | 20 x 10 x 9 mm | 15 cm/35 cm/34 cm      | 00384401014010         |

### INTERGARD Knitted Quadrifurcated

| Reference    | Diameter       | Length (Body/Branches) | Device identifier (DI) |
|--------------|----------------|------------------------|------------------------|
| IGKQ140706/1 | 14 x 7 x6 mm   | 15 cm/35 cm/34 cm      | 00384401012801         |
| IGKQ140707/1 | 14 x 7 x 7 mm  | 15 cm/35 cm/34 cm      | 00384401013846         |
| IGKQ160806/1 | 16 x 8 x 6 mm  | 15 cm/35 cm/34 cm      | 00384401012818         |
| IGKQ160807/1 | 16 x 8 x 7 mm  | 15 cm/35 cm/34 cm      | 00384401012825         |
| IGKQ160808/1 | 16 x 8 x 8 mm  | 15 cm/35 cm/34 cm      | 00384401012832         |
| IGKQ180908/1 | 18 x 9 x 8 mm  | 15 cm/35 cm/34 cm      | 00384401013853         |
| IGKQ201008/1 | 20 x 10 x 8 mm | 15 cm/35 cm/34 cm      | 00384401013877         |
| IGKQ201009/1 | 20 x 10 x 9 mm | 15 cm/35 cm/34 cm      | 00384401013860         |

### HEMAGARD Knitted Straight

| Reference   | Diameter | Length | Device identifier (DI) |
|-------------|----------|--------|------------------------|
| HGK0006-20  | 6 mm     | 20 cm  | 00384401014041         |
| HGK0006-40  | 6 mm     | 40 cm  | 00384401014058         |
| HGK0006-70  | 6 mm     | 70 cm  | 00384401014065         |
| HGK0006-100 | 6 mm     | 100 cm | 00384401015079         |
| HGK0007-20  | 7 mm     | 20 cm  | 00384401014096         |
| HGK0007-40  | 7 mm     | 40 cm  | 00384401014102         |
| HGK0007-70  | 7 mm     | 70 cm  | 00384401014119         |
| HGK0007-100 | 7 mm     | 100 cm | 00384401015086         |
| HGK0008-20  | 8 mm     | 20 cm  | 00384401014133         |
| HGK0008-40  | 8 mm     | 40 cm  | 00384401014140         |
| HGK0008-70  | 8 mm     | 70 cm  | 00384401014157         |
| HGK0008-100 | 8 mm     | 100 cm | 00384401014126         |
| HGK0010-20  | 10 mm    | 20 cm  | 00384401014201         |
| HGK0010-40  | 10 mm    | 40 cm  | 00384401014218         |
| HGK0010-70  | 10 mm    | 70 cm  | 00384401014225         |
| HGK0010-100 | 10 mm    | 100 cm | 00384401015093         |
| HGK0012-20  | 12 mm    | 20 cm  | 00384401014232         |
| HGK0012-40  | 12 mm    | 40 cm  | 00384401014249         |
| HGK0012-60  | 12 mm    | 60 cm  | 00384401015314         |
| HGK0014-20  | 14 mm    | 20 cm  | 00384401014256         |
| HGK0014-40  | 14 mm    | 40 cm  | 00384401014263         |
| HGK0016-20  | 16 mm    | 20 cm  | 00384401014270         |
| HGK0016-40  | 16 mm    | 40 cm  | 00384401014287         |
| HGK0018-20  | 18 mm    | 20 cm  | 00384401014294         |
| HGK0018-40  | 18 mm    | 40 cm  | 00384401014300         |
| HGK0020-20  | 20 mm    | 20 cm  | 00384401014317         |
| HGK0020-40  | 20 mm    | 40 cm  | 00384401014324         |
| HGK0022-20  | 22 mm    | 20 cm  | 00384401014331         |
| HGK0022-40  | 22 mm    | 40 cm  | 00384401014348         |
| HGK0024-20  | 24 mm    | 20 cm  | 00384401014355         |
| HGK0024-40  | 24 mm    | 40 cm  | 00384401014362         |

### HEMAGARD Knitted Straight Radially Supported (RS)

| Reference   | Diameter | Proximal/Distal length | Supported length | Total length | Device identifier (DI) |
|-------------|----------|------------------------|------------------|--------------|------------------------|
| HGK0006RS20 | 6 mm     | 35 cm/15 cm            | 20 cm            | 70 cm        | 00384401014072         |
| HGK0006RS30 | 6 mm     | 25 cm/15 cm            | 30 cm            | 70 cm        | 00384401014089         |
| HGK0008RS15 | 8 mm     | 40 cm/15 cm            | 15 cm            | 70 cm        | 00384401014164         |
| HGK0008RS20 | 8 mm     | 35 cm/15 cm            | 20 cm            | 70 cm        | 00384401014171         |
| HGK0008RS30 | 8 mm     | 25 cm/15 cm            | 30 cm            | 70 cm        | 00384401014188         |
| HGK0008RS45 | 8 mm     | 20 cm/20 cm            | 45 cm            | 85 cm        | 00384401014195         |

### HEMAGARD Knitted Axillo-bifemoral

| Reference | Diameter   | Distal length (Body/Branch) | Supported length (Body/Branch) | Total length (Body/Branch) | Device identifier (DI) |
|-----------|------------|-----------------------------|--------------------------------|----------------------------|------------------------|
| HGKAX0808 | 8 x 8 mm   | N/A                         | N/A                            | 100 cm/60 cm               | 00384401015109         |
| HGKAX1010 | 10 x 10 mm | N/A                         | N/A                            | 100 cm/60 cm               | 00384401014478         |



### HEMAGARD Knitted Axillo-bifemoral Radially Supported (RS)

| Reference          | Diameter      | Distal length (Body/Branch) | Supported length (Body/Branch) | Total length (Body/Branch) | Device identifier (DI) |
|--------------------|---------------|-----------------------------|--------------------------------|----------------------------|------------------------|
| HGKAX0808RS45/20   | 8 x 8 mm      | 20 cm/35 cm                 | 45 cm/20 cm                    | 85 cm/55 cm                | 00384401014447         |
| HGKAX0808RS45/30   | 8 x 8 mm      | 20 cm/25 cm                 | 45 cm/30 cm                    | 85 cm/55 cm                | 00384401014812         |
| HGKAX0808RS60/30   | 8 x 8 mm      | 20 cm/25 cm                 | 60 cm/30 cm                    | 100 cm/55 cm               | 00384401014454         |
| HGKAX100808RS35/20 | 10 x 8 x 8 mm | 25 cm/35 cm                 | 35 cm/20 cm                    | 85 cm/55 cm                | 00384401014461         |
| HGKAX080606RS35/20 | 8 x 6 x 6 mm  | 25 cm/35 cm                 | 35 cm/20 cm                    | 85 cm/55 cm                | 00384401014430         |

### HEMAGARD Knitted Bifurcated

| Reference | Diameter   | Length | Device identifier (DI) |
|-----------|------------|--------|------------------------|
| HGK1206   | 12 x 6 mm  | 50 cm  | 00384401014379         |
| HGK1207   | 12 x 7 mm  | 50 cm  | 00384401015017         |
| HGK1407   | 14 x 7 mm  | 50 cm  | 00384401014386         |
| HGK1408   | 14 x 8 mm  | 50 cm  | 00384401015031         |
| HGK1608   | 16 x 8 mm  | 50 cm  | 00384401014027         |
| HGK1609   | 16 x 9 mm  | 50 cm  | 00384401015048         |
| HGK1809   | 18 x 9 mm  | 50 cm  | 00384401014393         |
| HGK1810   | 18 x 10 mm | 50 cm  | 00384401015055         |
| HGK2010   | 20 x 10 mm | 50 cm  | 00384401014409         |
| HGK2011   | 20 x 11 mm | 50 cm  | 00384401015062         |
| HGK2211   | 22 x 11 mm | 50 cm  | 00384401014416         |
| HGK2412   | 24 x 12 mm | 50 cm  | 00384401014423         |

### HEMAGARD Knitted Trifurcated

| Reference   | Diameter       | Length (Body/Branches) | Device identifier (DI) |
|-------------|----------------|------------------------|------------------------|
| HGKT1407    | 14 x 7 mm      | 20 cm/35 cm            | 00384401014546         |
| HGKT1608    | 16 x 8 mm      | 20 cm/35 cm            | 00384401014577         |
| HGKT1809    | 18 x 9 mm      | 20 cm/35 cm            | 00384401014607         |
| HGKT2010    | 20 x 10 mm     | 20 cm/35 cm            | 00384401014638         |
| HGKT140707L | 14 x 7 x 7 mm  | 15 cm/35 cm/34 cm      | 00384401014553         |
| HGKT140707R | 14 x 7 x 7 mm  | 15 cm/35 cm/34 cm      | 00384401014560         |
| HGKT160808L | 16 x 8 x 8 mm  | 15 cm/35 cm/34 cm      | 00384401014584         |
| HGKT160808R | 16 x 8 x 8 mm  | 15 cm/35 cm/34 cm      | 00384401014591         |
| HGKT180908L | 18 x 9 x 8 mm  | 15 cm/35 cm/34 cm      | 00384401014614         |
| HGKT180908R | 18 x 9 x 8 mm  | 15 cm/35 cm/34 cm      | 00384401014621         |
| HGKT201009L | 20 x 10 x 9 mm | 15 cm/35 cm/34 cm      | 00384401014645         |
| HGKT201009R | 20 x 10 x 9 mm | 15 cm/35 cm/34 cm      | 00384401014652         |

### HEMAGARD Knitted Quadrifurcated

| Reference    | Diameter       | Length (Body/Branches) | Device identifier (DI) |
|--------------|----------------|------------------------|------------------------|
| HGKQ140706/1 | 14 x 7 x 6 mm  | 15 cm/35 cm/34 cm      | 00384401014485         |
| HGKQ140707/1 | 14 x 7 x 7 mm  | 15 cm/35 cm/34 cm      | 00384401014997         |
| HGKQ160806/1 | 16 x 8 x 6 mm  | 15 cm/35 cm/34 cm      | 00384401014492         |
| HGKQ160807/1 | 16 x 8 x 7 mm  | 15 cm/35 cm/34 cm      | 00384401014508         |
| HGKQ160808/1 | 16 x 8 x 8 mm  | 15 cm/35 cm/34 cm      | 00384401014515         |
| HGKQ180908/1 | 18 x 9 x 8 mm  | 15 cm/35 cm/34 cm      | 00384401014522         |
| HGKQ201008/1 | 20 x 10 x 8 mm | 15 cm/35 cm/34 cm      | 00384401015000         |
| HGKQ201009/1 | 20 x 10 x 9 mm | 15 cm/35 cm/34 cm      | 00384401014539         |



## 2. INTERGARD/HEMAGARD Knitted Ultrathin

The following codifications are used within this group:

- IGKUT (INTERGARD Knitted Ultrathin)
- HGKUT (HEMAGARD Knitted Ultrathin)
- RS (Radially Supported)

### INTERGARD Knitted Ultrathin Straight

| Reference    | Diameter | Length | Device identifier (DI) |
|--------------|----------|--------|------------------------|
| IGKUT0006-20 | 6 mm     | 20 cm  | 00384401007067         |
| IGKUT0006-40 | 6 mm     | 40 cm  | 00384401001225         |
| IGKUT0006-70 | 6 mm     | 70 cm  | 00384401001157         |
| IGKUT0007-20 | 7 mm     | 20 cm  | 00384401009252         |
| IGKUT0007-40 | 7 mm     | 40 cm  | 00384401001263         |
| IGKUT0007-70 | 7 mm     | 70 cm  | 00384401001164         |
| IGKUT0008-20 | 8 mm     | 20 cm  | 00384401007609         |
| IGKUT0008-40 | 8 mm     | 40 cm  | 00384401001270         |
| IGKUT0008-70 | 8 mm     | 70 cm  | 00384401001171         |

### INTERGARD Knitted Ultrathin Straight Radially Supported (RS)

| Reference     | Diameter | Proximal/Distal length | Supported length | Total length | Device identifier (DI) |
|---------------|----------|------------------------|------------------|--------------|------------------------|
| IGKUT0006RS20 | 6 mm     | 35 cm/15 cm            | 20 cm            | 70 cm        | 00384401001195         |
| IGKUT0006RS30 | 6 mm     | 25 cm/15 cm            | 30 cm            | 70 cm        | 00384401001201         |
| IGKUT0007RS20 | 7 mm     | 35 cm/15 cm            | 20 cm            | 70 cm        | 00384401001362         |
| IGKUT0007RS30 | 7 mm     | 25 cm/15 cm            | 30 cm            | 70 cm        | 00384401001379         |
| IGKUT0008RS15 | 8 mm     | 40 cm/15 cm            | 15 cm            | 70 cm        | 00384401006466         |
| IGKUT0008RS20 | 8 mm     | 35 cm/15 cm            | 20 cm            | 70 cm        | 00384401001294         |
| IGKUT0008RS30 | 8 mm     | 25 cm/15 cm            | 30 cm            | 70 cm        | 00384401001218         |

### HEMAGARD Knitted Ultrathin Straight

| Reference    | Diameter | Length | Device identifier (DI) |
|--------------|----------|--------|------------------------|
| HGKUT0006-20 | 6 mm     | 20 cm  | 00384401014669         |
| HGKUT0006-40 | 6 mm     | 40 cm  | 00384401014676         |
| HGKUT0006-70 | 6 mm     | 70 cm  | 00384401014683         |
| HGKUT0007-20 | 7 mm     | 20 cm  | 00384401014706         |
| HGKUT0007-40 | 7 mm     | 40 cm  | 00384401014713         |
| HGKUT0007-70 | 7 mm     | 70 cm  | 00384401014720         |
| HGKUT0008-20 | 8 mm     | 20 cm  | 00384401014751         |
| HGKUT0008-40 | 8 mm     | 40 cm  | 00384401014768         |
| HGKUT0008-70 | 8 mm     | 70 cm  | 00384401014775         |

### HEMAGARD Knitted Ultrathin Radially Supported (RS)

| Reference     | Diameter | Proximal/Distal length | Supported length | Total length | Device identifier (DI) |
|---------------|----------|------------------------|------------------|--------------|------------------------|
| HGKUT0006RS20 | 6 mm     | 35 cm/15 cm            | 20 cm            | 70 cm        | 00384401014690         |
| HGKUT0006RS30 | 6 mm     | 25 cm/15 cm            | 30 cm            | 70 cm        | 00384401014034         |
| HGKUT0007RS20 | 7 mm     | 35 cm/15 cm            | 20 cm            | 70 cm        | 00384401014737         |
| HGKUT0007RS30 | 7 mm     | 25 cm/15 cm            | 30 cm            | 70 cm        | 00384401014744         |
| HGKUT0008RS15 | 8 mm     | 40 cm/15 cm            | 15 cm            | 70 cm        | 00384401014782         |
| HGKUT0008RS20 | 8 mm     | 35 cm/15 cm            | 20 cm            | 70 cm        | 00384401014799         |
| HGKUT0008RS30 | 8 mm     | 25 cm/15 cm            | 30 cm            | 70 cm        | 00384401014805         |

### 3. INTERGARD / CARDIOROOT Woven

The following codifications are used within this group:

- IGW (INTERGARD Woven)
- HEWAA (Aortic Arch)
- HEWBRIDGE (Hemabridge)
- HEWROOT (CARDIOROOT)
- NGG (Uncrimped/Crimped)

#### **INTERGARD Woven Straight**

| Reference  | Diameter | Length | Device identifier (DI) |
|------------|----------|--------|------------------------|
| IGW0006-30 | 6 mm     | 30 cm  | 00384401000013         |
| IGW0008-30 | 8 mm     | 30 cm  | 00384401000037         |
| IGW0010-30 | 10 mm    | 30 cm  | 00384401000051         |
| IGW0012-15 | 12 mm    | 15 cm  | 00384401000075         |
| IGW0012-30 | 12 mm    | 30 cm  | 00384401000082         |
| IGW0014-15 | 14 mm    | 15 cm  | 00384401000099         |
| IGW0014-30 | 14 mm    | 30 cm  | 00384401000105         |
| IGW0016-15 | 16 mm    | 15 cm  | 00384401000112         |
| IGW0016-30 | 16 mm    | 30 cm  | 00384401000129         |
| IGW0018-15 | 18 mm    | 15 cm  | 00384401000136         |
| IGW0018-30 | 18 mm    | 30 cm  | 00384401000143         |
| IGW0020-15 | 20 mm    | 15 cm  | 00384401000150         |
| IGW0020-30 | 20 mm    | 30 cm  | 00384401000167         |
| IGW0022-15 | 22 mm    | 15 cm  | 00384401000174         |
| IGW0022-30 | 22 mm    | 30 cm  | 00384401000181         |
| IGW0022-60 | 22 mm    | 60 cm  | 00384401006459         |
| IGW0024-15 | 24 mm    | 15 cm  | 00384401000198         |
| IGW0024-30 | 24 mm    | 30 cm  | 00384401000204         |
| IGW0024-60 | 24 mm    | 60 cm  | 00384401005872         |
| IGW0026-15 | 26 mm    | 15 cm  | 00384401000211         |
| IGW0026-30 | 26 mm    | 30 cm  | 00384401000228         |
| IGW0026-60 | 26 mm    | 60 cm  | 00384401005889         |
| IGW0028-15 | 28 mm    | 15 cm  | 00384401000235         |
| IGW0028-30 | 28 mm    | 30 cm  | 00384401000242         |
| IGW0028-60 | 28 mm    | 60 cm  | 00384401005896         |
| IGW0030-15 | 30 mm    | 15 cm  | 00384401000259         |
| IGW0030-30 | 30 mm    | 30 cm  | 00384401000266         |
| IGW0030-60 | 30 mm    | 60 cm  | 00384401005902         |
| IGW0032-15 | 32 mm    | 15 cm  | 00384401000273         |
| IGW0032-30 | 32 mm    | 30 cm  | 00384401000280         |
| IGW0032-60 | 32 mm    | 60 cm  | 00384401007340         |
| IGW0034-15 | 34 mm    | 15 cm  | 00384401000297         |
| IGW0034-30 | 34 mm    | 30 cm  | 00384401000303         |
| IGW0036-15 | 36 mm    | 15 cm  | 00384401000341         |
| IGW0036-30 | 36 mm    | 30 cm  | 00384401000310         |
| IGW0038-30 | 38 mm    | 30 cm  | 00384401000334         |

### INTERGARD Woven Bifurcated

| Reference | Diameter   | Length | Device identifier (DI) |
|-----------|------------|--------|------------------------|
| IGW1206   | 12 x 6 mm  | 50 cm  | 00384401000532         |
| IGW1407   | 14 x 7 mm  | 50 cm  | 00384401000549         |
| IGW1608   | 16 x 8 mm  | 50 cm  | 00384401000556         |
| IGW1809   | 18 x 9 mm  | 50 cm  | 00384401000563         |
| IGW2010   | 20 x 10 mm | 50 cm  | 00384401000570         |
| IGW2211   | 22 x 11 mm | 50 cm  | 00384401000587         |
| IGW2412   | 24 x 12 mm | 50 cm  | 00384401000594         |

### INTERGARD Woven Thoracic Aortic Graft

| Reference     | Diameter | Length | Device identifier (DI) |
|---------------|----------|--------|------------------------|
| IGW0024-15NGG | 24 mm    | 15 cm  | 00384401012894         |
| IGW0026-15NGG | 26 mm    | 15 cm  | 00384401012177         |
| IGW0028-15NGG | 28 mm    | 15 cm  | 00384401012184         |
| IGW0030-15NGG | 30 mm    | 15 cm  | 00384401012191         |
| IGW0032-15NGG | 32 mm    | 15 cm  | 00384401012207         |
| IGW0034-15NGG | 34 mm    | 15 cm  | 00384401012214         |

### INTERGARD Woven Aortic Arch

| Reference         | Diameter                | Length                    | Device identifier (DI) |
|-------------------|-------------------------|---------------------------|------------------------|
| HEWAA2010080810/1 | 20 x 10 x 8 x 8 x 10 mm | 50 x 30 x 30 x 30 x 30 cm | 00384401103868         |
| HEWAA2210080810/1 | 22 x 10 x 8 x 8 x 10 mm | 50 x 30 x 30 x 30 x 30 cm | 00384401010722         |
| HEWAA2410080810/1 | 24 x 10 x 8 x 8 x 10 mm | 50 x 30 x 30 x 30 x 30 cm | 00384401010739         |
| HEWAA2610080810/1 | 26 x 10 x 8 x 8 x 10 mm | 50 x 30 x 30 x 30 x 30 cm | 00384401010746         |
| HEWAA2810080810/1 | 28 x 10 x 8 x 8 x 10 mm | 50 x 30 x 30 x 30 x 30 cm | 00384401010753         |
| HEWAA3010080810/1 | 30 x 10 x 8 x 8 x 10 mm | 50 x 30 x 30 x 30 x 30 cm | 00384401010760         |
| HEWAA3210080810/1 | 32 x 10 x 8 x 8 x 10 mm | 50 x 30 x 30 x 30 x 30 cm | 00384401103851         |
| HEWAA3410080810/1 | 34 x 10 x 8 x 8 x 10 mm | 50 x 30 x 30 x 30 x 30 cm | 00384401103844         |

### INTERGARD Woven Hemabridge

| Reference     | Diameter   | Length     | Device identifier (DI) |
|---------------|------------|------------|------------------------|
| HEW2010BRIDGE | 20 x 10 mm | 35 x 40 cm | 00384401006930         |
| HEW2210BRIDGE | 22 x 10 mm | 35 x 40 cm | 00384401007265         |
| HEW2410BRIDGE | 24 x 10 mm | 35 x 40 cm | 00384401001232         |
| HEW2610BRIDGE | 26 x 10 mm | 35 x 40 cm | 00384401001249         |
| HEW2810BRIDGE | 28 x 10 mm | 35 x 40 cm | 00384401001010         |
| HEW3010BRIDGE | 30 x 10 mm | 35 x 40 cm | 00384401001027         |
| HEW3210BRIDGE | 32 x 10 mm | 35 x 40 cm | 00384401001386         |
| HEW3410BRIDGE | 34 x 10 mm | 35 x 40 cm | 00384401001034         |
| HEW3610BRIDGE | 36 x 10 mm | 35 x 40 cm | 00384401006190         |

## CARDIOROOT Woven Bulged Graft

| Reference   | Body diameter | Bulge diameter | Distal body length | Bulge length | Proximal body length | Device identifier (DI) |
|-------------|---------------|----------------|--------------------|--------------|----------------------|------------------------|
| HEWROOT0024 | 24 mm         | 32 mm          | 15 cm              | 24 mm        | 1 cm                 | 00384401013884         |
| HEWROOT0026 | 26 mm         | 34 mm          | 15 cm              | 26 mm        | 1 cm                 | 00384401013891         |
| HEWROOT0028 | 28 mm         | 36 mm          | 15 cm              | 28 mm        | 1 cm                 | 00384401013907         |
| HEWROOT0030 | 30 mm         | 38 mm          | 15 cm              | 30 mm        | 1 cm                 | 00384401013914         |
| HEWROOT0032 | 32 mm         | 40 mm          | 15 cm              | 32 mm        | 1 cm                 | 00384401013921         |
| HEWROOT0034 | 34 mm         | 42 mm          | 15 cm              | 34 mm        | 1 cm                 | 00384401013938         |

## 4. HEMAPATCH/HEMAGARD PATCH Knitted and HEMACAROTID/HEMAGARD CAROTID Patch Knitted

The following codifications are used within this group:

- HEK (HEMAPATCH Knitted)
- HGK (HEMAGARD PATCH Knitted)
- TP (Tapered)
- P (Patch)
- CP (Carotid Patch)

### HEMAPATCH Knitted

| Reference       | Dimensions   | Device identifier (DI) |
|-----------------|--------------|------------------------|
| HEK25/50P (1)   | 25 x 50 mm   | 00384401001560         |
| HEK25/100P (1)  | 25 x 100 mm  | 00384401001591         |
| HEK50/50P (1)   | 50 x 50 mm   | 00384401001577         |
| HEK75/75P (1)   | 75 x 75 mm   | 00384401001515         |
| HEK100/100P (1) | 100 x 100 mm | 00384401001522         |
| HEK10/140P (1)  | 10 x 140 mm  | 00384401007661         |
| HEK20/140P (1)  | 20 x 140 mm  | 00384401010654         |

### HEMAGARD PATCH Knitted

| Reference       | Dimensions   | Device identifier (DI) |
|-----------------|--------------|------------------------|
| HGK25/50P (1)   | 25 x 50 mm   | 00384401014829         |
| HGK25/75P (1)   | 25 x 75 mm   | 00384401015024         |
| HGK25/100P (1)  | 25 x 100 mm  | 00384401014836         |
| HGK25/150P (1)  | 25 x 150 mm  | 00384401015116         |
| HGK50/50P (1)   | 50 x 50 mm   | 00384401014843         |
| HGK50/75P (1)   | 50 x 75 mm   | 00384401015123         |
| HGK50/150P (1)  | 50 x 150 mm  | 00384401015130         |
| HGK75/75P (1)   | 75 x 75 mm   | 00384401014850         |
| HGK100/100P (1) | 100 x 100 mm | 00384401014867         |
| HGK10/140P (1)  | 10 x 140 mm  | 00384401014874         |
| HGK20/140P (1)  | 20 x 140 mm  | 00384401014881         |

### HEMACAROTID Patch Knitted

| Reference      | Dimensions | Device identifier (DI) |
|----------------|------------|------------------------|
| HEK06/75CP (1) | 6 x 75 mm  | 00384401001423         |
| HEK08/75CP (1) | 8 x 75 mm  | 00384401001416         |
| HEK10/75CP (1) | 10 x 75 mm | 00384401001430         |
| HEK12/75CP (1) | 12 x 75 mm | 00384401001447         |
| HEK14/75CP (1) | 14 x 75 mm | 00384401001454         |

### HEMAGARD Carotid Patch Knitted

| Reference        | Dimensions | Device identifier (DI) |
|------------------|------------|------------------------|
| HGK10/75CP (1)   | 10 x 75 mm | 00384401014898         |
| HGK12/75CP (1)   | 12 x 75 mm | 00384401014904         |
| HGK14/75CP (1)   | 14 x 75 mm | 00384401014911         |
| HGKTP06/75CP (1) | 6 x 75 mm  | 00384401015178         |
| HGKTP08/75CP (1) | 8 x 75 mm  | 00384401015185         |

## 5. HEMACAROTID and HEMAGARD CAROTID Knitted Ultrathin Patches

The following codifications are used within this group:

- HEK (HEMACAROTID Knitted)
- HGK (HEMAGARD Knitted)
- TP (Tapered)
- UT (Ultrathin)
- CP (Carotid Patch)
- CPUT (Carotid Ultrathin Patch)

### HEMACAROTID Patch Knitted Ultrathin

| Reference         | Dimensions  | Device identifier (DI) |
|-------------------|-------------|------------------------|
| HEK06/75CPUT (1)  | 6 x 75 mm   | 00384401001461         |
| HEK08/75CPUT (1)  | 8 x 75 mm   | 00384401001478         |
| HEK10/75CPUT (1)  | 10 x 75 mm  | 00384401001485         |
| HEK12/75CPUT (1)  | 12 x 75 mm  | 00384401001492         |
| HEK14/75CPUT (1)  | 14 x 75 mm  | 00384401001508         |
| HEK10/150CPUT (1) | 10 x 150 mm | 00384401011224         |
| HEK25/100CPUT (1) | 25 x 100 mm | 00384401011248         |
| HEK06/120CPUT (1) | 6 x 120 mm  | 00384401010708         |
| HEK08/120CPUT (1) | 8 x 120 mm  | 00384401010715         |

### HEMAGARD CAROTID Patch Knitted Ultrathin

| Reference           | Dimensions  | Device identifier (DI) |
|---------------------|-------------|------------------------|
| HGK10/75CPUT (1)    | 10 x 75 mm  | 00384401014928         |
| HGK12/75CPUT (1)    | 12 x 75 mm  | 00384401014935         |
| HGK14/75CPUT (1)    | 14 x 75 mm  | 00384401014942         |
| HGK25/75CPUT (1)    | 25 x 75 mm  | 00384401015147         |
| HGK25/100CPUT (1)   | 25 x 100 mm | 00384401014966         |
| HGK10/150CPUT (1)   | 10 x 150 mm | 00384401014959         |
| HGK25/150CPUT (1)   | 25 x 150 mm | 00384401015154         |
| HGKTP06/75CPUT (1)  | 6 x 75 mm   | 00384401015192         |
| HGKTP08/75CPUT (1)  | 8 x 75 mm   | 00384401015208         |
| HGKTP06/120CPUT (1) | 6 x 120 mm  | 00384401014973         |
| HGKTP08/120CPUT (1) | 8 x 120 mm  | 00384401014980         |
| HGKTP08/150CPUT (1) | 8 x 150 mm  | 00384401015161         |

## 6. HEMAPATCH Woven

The following codifications are used within this group:

- HEW (HEMAPATCH Woven)
- P (Patch)

### **HEMAPATCH Woven**

| <b>Reference</b> | <b>Dimensions</b> | <b>Device identifier (DI)</b> |
|------------------|-------------------|-------------------------------|
| HEW25/50P (1)    | 25 x 50 mm        | 00384401001584                |
| HEW25/100P (1)   | 25 x 100 mm       | 00384401003359                |
| HEW50/50P (1)    | 50 x 50 mm        | 00384401001539                |
| HEW75/75P (1)    | 75 x 75 mm        | 00384401001546                |
| HEW100/100P (1)  | 100 x 100 mm      | 00384401001553                |





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. G7AO 103025 0016 Rev. 01**

**Manufacturer:** **INTERVASCULAR SAS**  
Z.I. Athélia 1  
13705 La Ciotat Cedex  
FRANCE

**Product:** **Vascular Grafts**  
**INTERGARD Standard**

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 the directive 93/42/EEC Annex II (4) and Regulation (EU) 722/2012 on medical devices manufactured utilizing tissues of animal origin. The design of the devices conforms to the requirements of the Directive and the Regulation. If a certificate of the European Directorate for the Quality of Medicines (EDQM) has been issued for the respective material of animal origin, the validity of our certificate is associated with the validity of the EDQM certificate. Any changes of the EDQM certificate need to be reported immediately to TÜV SÜD Product Service GmbH by a change notification. For marketing of these devices an additional Annex II without (4) certificate is mandatory. See also notes overleaf.

**Report no.:** 713161854

**Valid from:** 2020-05-11

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

**Date,** 2020-05-11

Christoph Dicks  
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



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. G7AO 103025 0016 Rev. 01**

**Model(s): INTERGARD Standard - Collagen Coated  
Vascular Grafts and Patches**

## Parameters:

| Product name      | Product configuration | Product reference |
|-------------------|-----------------------|-------------------|
| INTERGARD Knitted | Straight              | IGK0006-20        |
|                   |                       | IGK0006-40        |
|                   |                       | IGK0006-70        |
|                   |                       | IGK0007-20        |
|                   |                       | IGK0007-40        |
|                   |                       | IGK0007-70        |
|                   |                       | IGK0008-20        |
|                   |                       | IGK0008-40        |
|                   |                       | IGK0008-70        |
|                   |                       | IGK0008-100       |
|                   |                       | IGK0010-20        |
|                   |                       | IGK0010-40        |
|                   |                       | IGK0010-70        |
|                   |                       | IGK0012-20        |
|                   |                       | IGK0012-40        |
|                   |                       | IGK0014-20        |
|                   |                       | IGK0014-40        |
|                   |                       | IGK0016-20        |
|                   |                       | IGK0016-40        |
|                   |                       | IGK0018-20        |
|                   |                       | IGK0018-40        |
|                   |                       | IGK0020-20        |
|                   |                       | IGK0020-40        |
|                   |                       | IGK0022-20        |
| IGK0022-40        |                       |                   |
| IGK0024-20        |                       |                   |
| IGK0024-40        |                       |                   |

TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT





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. G7AO 103025 0016 Rev. 01**

|                   |  |                    |
|-------------------|--|--------------------|
| INTERGARD Knitted | Straight Radially Supported (RS)         | IGK0006RS20        |
|                   |  | IGK0006RS30        |
|                   |  | IGK0008RS15        |
|                   |  | IGK0008RS20        |
|                   |  | IGK0008RS30        |
|                   |  | IGK0008RS45        |
| INTERGARD Knitted | Axillo-bifemoral                         | IGKAX1010          |
| INTERGARD Knitted | Axillo-bifemoral Radially Supported (RS) | IGKAX0808RS45/20   |
|                   |  | IGKAX0808RS45/30   |
|                   |  | IGKAX0808RS60/30   |
|                   |  | IGKAX100808RS35/20 |
|                   |  | IGKAX080606RS35/20 |
| INTERGARD Knitted | Bifurcated                               | IGK1206            |
|                   |  | IGK1407            |
|                   |  | IGK1608            |
|                   |  | IGK1809            |
|                   |  | IGK2010            |
|                   |  | IGK2211            |
|                   |  | IGK2412            |
|                   |  | IGKT1407           |
| INTERGARD Knitted | Trifurcated                              | IGKT1608           |
|                   |  | IGKT1809           |
|                   |  | IGKT2010           |
|                   |  | IGKT140707L        |
|                   |  | IGKT140707R        |
|                   |  | IGKT160808L        |
|                   |  | IGKT160808R        |
|                   |  | IGKT180908L        |
|                   |  | IGKT180908R        |
|                   |  | IGKT201009L        |
|                   |  | IGKT201009R        |
|                   |  | INTERGARD Knitted  |
| IGKQ140707/1      |  |                    |
| IGKQ160806/1      |  |                    |
| IGKQ160807/1      |  |                    |
| IGKQ160808/1      |  |                    |
| IGKQ180908/1      |  |                    |
| IGKQ201008/1      |  |                    |
| IGKQ201009/1      |  |                    |

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



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. G7AO 103025 0016 Rev. 01**

|                  |                                  |             |
|------------------|----------------------------------|-------------|
| HEMAGARD Knitted | Straight                         | HGK0006-20  |
|                  |                                  | HGK0006-40  |
|                  |                                  | HGK0006-70  |
|                  |                                  | HGK0006-100 |
|                  |                                  | HGK0007-20  |
|                  |                                  | HGK0007-40  |
|                  |                                  | HGK0007-70  |
|                  |                                  | HGK0007-100 |
|                  |                                  | HGK0008-20  |
|                  |                                  | HGK0008-40  |
|                  |                                  | HGK0008-70  |
|                  |                                  | HGK0008-100 |
|                  |                                  | HGK0010-20  |
|                  |                                  | HGK0010-40  |
|                  |                                  | HGK0010-70  |
|                  |                                  | HGK0010-100 |
|                  |                                  | HGK0012-20  |
|                  |                                  | HGK0012-40  |
|                  |                                  | HGK0012-60  |
|                  |                                  | HGK0014-20  |
|                  |                                  | HGK0014-40  |
|                  |                                  | HGK0016-20  |
|                  |                                  | HGK0016-40  |
|                  |                                  | HGK0018-20  |
| HGK0018-40       |                                  |             |
| HGK0020-20       |                                  |             |
| HGK0020-40       |                                  |             |
| HGK0022-20       |                                  |             |
| HGK0022-40       |                                  |             |
| HGK0024-20       |                                  |             |
| HGK0024-40       |                                  |             |
| HEMAGARD Knitted | Straight Radially Supported (RS) | HGK0006RS20 |
|                  |                                  | HGK0006RS30 |
|                  |                                  | HGK0008RS15 |
|                  |                                  | HGK0008RS20 |
|                  |                                  | HGK0008RS30 |
| HGK0008RS45      |                                  |             |

TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17



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. G7AO 103025 0016 Rev. 01**

|                  |  |                    |
|------------------|--|--------------------|
| HEMAGARD Knitted | Axillo-bifemoral                         | HGKAX0808          |
|                  |  | HGKAX1010          |
| HEMAGARD Knitted | Axillo-bifemoral Radially Supported (RS) | HGKAX0808RS45/20   |
|                  |  | HGKAX0808RS45/30   |
|                  |  | HGKAX0808RS60/30   |
|                  |  | HGKAX100808RS35/20 |
| HEMAGARD Knitted | Bifurcated                               | HGK1206            |
|                  |  | HGK1207            |
|                  |  | HGK1407            |
|                  |  | HGK1408            |
|                  |  | HGK1608            |
|                  |  | HGK1609            |
|                  |  | HGK1809            |
|                  |  | HGK1810            |
|                  |  | HGK2010            |
|                  |  | HGK2011            |
|                  |  | HGK2211            |
|                  |  | HGK2412            |
| HEMAGARD Knitted | Trifurcated                              | HGKT1407           |
|                  |  | HGKT1608           |
|                  |  | HGKT1809           |
|                  |  | HGKT2010           |
|                  |  | HGKT140707L        |
|                  |  | HGKT140707R        |
|                  |  | HGKT160808L        |
|                  |  | HGKT160808R        |
|                  |  | HGKT180908L        |
|                  |  | HGKT180908R        |
|                  |  | HGKT201009L        |
| HGKT201009R      |  |                    |
| HEMAGARD Knitted | Quadrifurcated                           | HGKQ140706/1       |
|                  |  | HGKQ140707/1       |
|                  |  | HGKQ160806/1       |
|                  |  | HGKQ160807/1       |
|                  |  | HGKQ160808/1       |
|                  |  | HGKQ180908/1       |
|                  |  | HGKQ201008/1       |
| HGKQ201009/1     |  |                    |

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT





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. G7AO 103025 0016 Rev. 01**

|                             |                                  |               |
|-----------------------------|----------------------------------|---------------|
| INTERGARD Knitted Ultrathin | Straight                         | IGKUT0006-20  |
|                             |                                  | IGKUT0006-40  |
|                             |                                  | IGKUT0006-70  |
|                             |                                  | IGKUT0007-20  |
|                             |                                  | IGKUT0007-40  |
|                             |                                  | IGKUT0007-70  |
|                             |                                  | IGKUT0008-20  |
|                             |                                  | IGKUT0008-40  |
|                             |                                  | IGKUT0008-70  |
| INTERGARD Knitted Ultrathin | Straight Radially Supported (RS) | IGKUT0006RS20 |
|                             |                                  | IGKUT0006RS30 |
|                             |                                  | IGKUT0007RS20 |
|                             |                                  | IGKUT0007RS30 |
|                             |                                  | IGKUT0008RS15 |
|                             |                                  | IGKUT0008RS20 |
| HEMAGARD Knitted Ultrathin  | Straight                         | HGKUT0006-20  |
|                             |                                  | HGKUT0006-40  |
|                             |                                  | HGKUT0006-70  |
|                             |                                  | HGKUT0007-20  |
|                             |                                  | HGKUT0007-40  |
|                             |                                  | HGKUT0007-70  |
|                             |                                  | HGKUT0008-20  |
|                             |                                  | HGKUT0008-40  |
|                             |                                  | HGKUT0008-70  |
| HEMAGARD Knitted Ultrathin  | Straight Radially Supported (RS) | HGKUT0006RS20 |
|                             |                                  | HGKUT0006RS30 |
|                             |                                  | HGKUT0007RS20 |
|                             |                                  | HGKUT0007RS30 |
|                             |                                  | HGKUT0008RS15 |
|                             |                                  | HGKUT0008RS20 |

TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17





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. G7AO 103025 0016 Rev. 01**

|                 |            |            |
|-----------------|------------|------------|
| Intergard Woven | Straight   | IGW0006-30 |
|                 |            | IGW0008-30 |
|                 |            | IGW0010-30 |
|                 |            | IGW0012-15 |
|                 |            | IGW0012-30 |
|                 |            | IGW0014-15 |
|                 |            | IGW0014-30 |
|                 |            | IGW0016-15 |
|                 |            | IGW0016-30 |
|                 |            | IGW0018-15 |
|                 |            | IGW0018-30 |
|                 |            | IGW0020-15 |
|                 |            | IGW0020-30 |
|                 |            | IGW0022-15 |
|                 |            | IGW0022-30 |
|                 |            | IGW0022-60 |
|                 |            | IGW0024-15 |
|                 |            | IGW0024-30 |
|                 |            | IGW0024-60 |
|                 |            | IGW0026-15 |
|                 |            | IGW0026-30 |
|                 |            | IGW0026-60 |
|                 |            | IGW0028-15 |
|                 |            | IGW0028-30 |
|                 |            | IGW0028-60 |
|                 |            | IGW0030-15 |
| IGW0030-30      |            |            |
| IGW0030-60      |            |            |
| IGW0032-15      |            |            |
| IGW0032-30      |            |            |
| IGW0032-60      |            |            |
| IGW0034-15      |            |            |
| IGW0034-30      |            |            |
| IGW0036-15      |            |            |
| IGW0036-30      |            |            |
| IGW0038-30      |            |            |
| Intergard Woven | Bifurcated | IGW1206    |
|                 |            | IGW1407    |
|                 |            | IGW1608    |
|                 |            | IGW1809    |
|                 |            | IGW2010    |
|                 |            | IGW2211    |
| IGW2412         |            |            |

TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFIKAT



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. G7AO 103025 0016 Rev. 01**

|                   |                 |                   |
|-------------------|-----------------|-------------------|
| Intergard Woven   | Thoracic Aortic | IGW0024-15NGG     |
|                   |                 | IGW0026-15NGG     |
|                   |                 | IGW0028-15NGG     |
|                   |                 | IGW0030-15NGG     |
|                   |                 | IGW0032-15NGG     |
|                   |                 | IGW0034-15NGG     |
| Intergard Woven   | Aortic Arch     | HEWAA2010080810/1 |
|                   |                 | HEWAA2210080810/1 |
|                   |                 | HEWAA2410080810/1 |
|                   |                 | HEWAA2610080810/1 |
|                   |                 | HEWAA2810080810/1 |
|                   |                 | HEWAA3010080810/1 |
|                   |                 | HEWAA3210080810/1 |
| HEWAA3410080810/1 |                 |                   |
| Intergard Woven   | Hemabridge      | HEW2010BRIDGE     |
|                   |                 | HEW2210BRIDGE     |
|                   |                 | HEW2410BRIDGE     |
|                   |                 | HEW2610BRIDGE     |
|                   |                 | HEW2810BRIDGE     |
|                   |                 | HEW3010BRIDGE     |
|                   |                 | HEW3210BRIDGE     |
|                   |                 | HEW3410BRIDGE     |
|                   |                 | HEW3610BRIDGE     |
| Cardioroot Woven  | Bulged Graft    | HEWROOT0024       |
|                   |                 | HEWROOT0026       |
|                   |                 | HEWROOT0028       |
|                   |                 | HEWROOT0030       |
|                   |                 | HEWROOT0032       |
| HEMAPATCH Knitted | Patch           | HEK25/50P (1)     |
|                   |                 | HEK25/100P (1)    |
|                   |                 | HEK50/50P (1)     |
|                   |                 | HEK75/75P (1)     |
|                   |                 | HEK100/100P (1)   |
|                   |                 | HEK10/140P (1)    |
|                   |                 | HEK20/140P (1)    |

TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFIKAT





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. G7AO 103025 0016 Rev. 01**

|                                     |                           |                   |
|-------------------------------------|---------------------------|-------------------|
| HEMAGARD PATCH Knitted              | Patch                     | HGK25/50P (1)     |
|                                     | Patch                     | HGK25/75P (1)     |
|                                     | Patch                     | HGK25/100P (1)    |
|                                     | Patch                     | HGK25/150P (1)    |
|                                     | Patch                     | HGK50/50P (1)     |
|                                     | Patch                     | HGK50/75P (1)     |
|                                     | Patch                     | HGK50/150P (1)    |
|                                     | Patch                     | HGK75/75P (1)     |
|                                     | Patch                     | HGK100/100P (1)   |
|                                     | Patch                     | HGK10/140P (1)    |
|                                     | Patch                     | HGK20/140P (1)    |
|                                     | HEMACAROTID Patch Knitted | Patch             |
| Patch                               |                           | HEK08/75CP (1)    |
| Patch                               |                           | HEK10/75CP (1)    |
| Patch                               |                           | HEK12/75CP (1)    |
| Patch                               |                           | HEK14/75CP (1)    |
| HEMAGARD CAROTID Patch Knitted      | Patch                     | HGK10/75CP (1)    |
|                                     | Patch                     | HGK12/75CP (1)    |
|                                     | Patch                     | HGK14/75CP (1)    |
|                                     | Patch Tapered             | HGKTP06/75CP (1)  |
|                                     | Patch Tapered             | HGKTP08/75CP (1)  |
| HEMACAROTID Patch Knitted Ultrathin | Patch                     | HEK06/75CPUT (1)  |
|                                     | Patch                     | HEK08/75CPUT (1)  |
|                                     | Patch                     | HEK10/75CPUT (1)  |
|                                     | Patch                     | HEK12/75CPUT (1)  |
|                                     | Patch                     | HEK14/75CPUT (1)  |
|                                     | Patch                     | HEK10/150CPUT (1) |
|                                     | Patch                     | HEK25/100CPUT (1) |
|                                     | Patch                     | HEK06/120CPUT (1) |
|                                     | Patch                     | HEK08/120CPUT (1) |

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE



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. G7AO 103025 0016 Rev. 01**

|  |                 |                     |
|--|-----------------|---------------------|
| HEMAGARD CAROTID Patch Knitted Ultrathin | Patch           | HGK10/75CPUT (1)    |
|  | Patch           | HGK12/75CPUT (1)    |
|  | Patch           | HGK14/75CPUT (1)    |
|  | Patch           | HGK25/75CPUT (1)    |
|  | Patch           | HGK25/100CPUT (1)   |
|  | Patch           | HGK10/150CPUT (1)   |
|  | Patch           | HGK25/150CPUT (1)   |
|  | Patch Tapered   | HGKTP06/75CPUT (1)  |
|  | Patch Tapered   | HGKTP08/75CPUT (1)  |
|  | Patch Tapered   | HGKTP06/120CPUT (1) |
|  | Patch Tapered   | HGKTP08/120CPUT (1) |
|  | Patch Tapered   | HGKTP08/150CPUT (1) |
|  | HEMAPATCH Woven | Patch               |
| Patch                                    |                 | HEW25/100P (1)      |
| Patch                                    |                 | HEW50/50P (1)       |
| Patch                                    |                 | HEW75/75P (1)       |
| Patch                                    |                 | HEW100/100P (1)     |

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17



# Certificate

No. Q5 103025 0007 Rev. 02

**Holder of Certificate:** **INTERVASCULAR SAS**

Z.I. Athélie 1  
13705 La Ciotat Cedex  
FRANCE

**Facility(ies):**

INTERVASCULAR SAS  
Z.I. Athélie 1, 13705 La Ciotat Cedex, FRANCE

See Scope of Certificate

**Certification Mark:**



**Scope of Certificate:** **Design and development, production and distribution of collagen coated vascular grafts and patches with or without drug coating and graft sizers.**

**Applied Standard(s):**

EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 103025 0007 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_103025_0007_Rev_02)

**Report No.:** 713186119

**Valid from:** 2021-07-02

**Valid until:** 2023-12-31

**Date,** 2021-07-02

Christoph Dicks  
Head of Certification/Notified Body



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

Full Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 103025 0006 Rev. 02**

**Manufacturer:** **INTERVASCULAR SAS**  
Z.I. Athélia 1  
13705 La Ciotat Cedex  
FRANCE

**Product Category(ies):** **Collagen coated vascular grafts and patches with or without drug coating**

**Graft sizers**

**Collagen coated vascular grafts and patches**  
**Antimicrobial collagen coated vascular grafts and patches with silver**

**Collagen coated and heparin bonded vascular grafts and patches**  
**Antimicrobial collagen coated vascular grafts with silver and triclosan**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** 713171814

**Valid from:** 2020-06-24

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

**Date,** 2020-06-24

Christoph Dicks  
Head of Certification/Notified Body

TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17