



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**

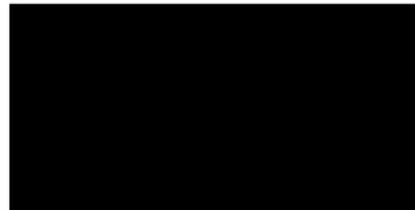
The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with the directive 93/42/EEC Annex II (4) and Regulation (EU) 722/2012 on medical devices manufactured utilizing tissues of animal origin. The design 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 ◆ 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 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  
 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



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
		HGKAX080606RS35/20
HEMAGARD Knitted	Bifurcated	HGK1206
		HGK1207
		HGK1407
		HGK1408
		HGK1608
		HGK1609
		HGK1809
		HGK1810
		HGK2010
		HGK2011
		HGK2211
		HGK2412
		HEMAGARD Knitted
HGKT1608		
HGKT1809		
HGKT2010		
HGKT140707L		
HGKT140707R		
HGKT160808L		
HGKT160808R		
HGKT180908L		
HGKT180908R		
HGKT201009L		
HGKT201009R		
HEMAGARD Knitted	Quadrifurcated	
		HGKQ140707/1
		HGKQ160806/1
		HGKQ160807/1
		HGKQ160808/1
		HGKQ180908/1
		HGKQ201008/1
		HGKQ201009/1

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



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 ◆ 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 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  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ 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 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  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17