



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 0017 Rev. 00

Manufacturer:

INTERVASCULAR SAS

Z.I. Athélia 1
13705 La Ciotat Cedex
FRANCE

Product:

**Vascular Grafts
INTERGARD Silver**

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.:

713154919

Valid from:

2019-08-13

Valid until:

2024-03-31

Date,

2019-08-13

Stefan Preiß

Head of Certification/Notified Body



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Model(s):

**INTERGARD Silver - Antimicrobial Collagen
Coated Vascular Grafts & Patches**

Facility(ies):

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

Parameters:

Product name	Product configuration	Product reference
INTERGARD Silver Knitted	Straight	IGK0006-20S
		IGK0008-20S
		IGK0012-20S
		IGK0014-20S
		IGK0016-20S
		IGK0018-20S
		IGK0020-20S
		IGK0022-20S
		IGK0024-20S
		IGK0006-40S
		IGK0007-40S
		IGK0008-40S
		IGK0010-40S
		IGK0012-40S
		IGK0014-40S
		IGK0016-40S
		IGK0018-40S
		IGK0020-40S
		IGK0022-40S
		IGK0024-40S
INTERGARD Silver Knitted	Straight Supported (RS)	IGK0006-70S
		IGK0007-70S
		IGK0008-70S
		IGK0010-70S
		IGK0006RS20S
		IGK0006RS30S
		IGK0006RS45S
		IGK0008RS15S
		IGK0008RS20S
		IGK0008RS45S
		IGK0008RS30S
		IGK0008RS60S
		IGK0008RS15-40S
		IGK0010RS10-40S
		IGK0006RS30NGGS



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INTERGARD Silver Knitted	Bifurcated	IGK1206S
		IGK1407S
		IGK1608S
		IGK1809S
		IGK2010S
		IGK2211S
		IGK2412S
INTERGARD Silver Knitted	Axilo-bifemoral	IGKAX0808S
INTERGARD Silver Knitted	Axillo bifemoral Radially Supported (RS)	IGKAX0808RS45/20S
		IGKAX0808RS45/30S
		IGKAX0808RS60/30S
INTERGARD Silver Knitted Ultrathin	Straight	IGKUT0006-40S
		IGKUT0007-40S
		IGKUT0008-40S
		IGKUT0006-70S
		IGKUT0007-70S
		IGKUT0008-70S
INTERGARD Silver Knitted Ultrathin	Straight Radially Supported (RS)	IGKUT0006RS20S
		IGKUT0006RS30S
		IGKUT0007RS20S
		IGKUT0007RS30S
		IGKUT0008RS15S
		IGKUT0008RS20S
		IGKUT0008RS30S
		IGKUT0008RS10-40S
		IGKUT0008RS15-40S

