

DECLARATION OF CONFORMITY

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

PRODUCT : Vascular Grafts
INTERGARD Silver

MODEL : INTERGARD Silver – Antimicrobial Collagen Coated Vascular Graft and Patches

Product Category	Product Name
Antimicrobial Knitted Collagen Coated Vascular Grafts	INTERGARD Silver Knitted
Antimicrobial Knitted Ultrathin Collagen Coated Vascular Grafts	INTERGARD Silver Knitted Ultrathin
Antimicrobial Woven Collagen Coated Vascular Grafts	INTERGARD Silver Woven
Antimicrobial Knitted Ultrathin Collagen Coated Vascular Patches	HEMAPATCH Silver Knitted Ultrathin

(See Appendix 1 for product references)

CLASSIFICATION: Class III (MDD 93/42/EEC Annex IX, rules 8, 13 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 0017 Rev. 00 (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 Silver Knitted

The following codifications are used within this group:

- IGK (INTERGARD Knitted)
- RS (Radially Supported)
- NGG (Uncrimped/Crimped)
- S (Silver)
- AX (Axillo-bifemoral)

INTERGARD Silver Knitted Straight

Reference	Diameter	Length	Device Identifier (DI)
IGK0006-20S	6 mm	20 cm	00384401010678
IGK0008-20S	8 mm	20 cm	00384401010661
IGK0012-20S	12 mm	20 cm	00384401009665
IGK0014-20S	14 mm	20 cm	00384401009689
IGK0016-20S	16 mm	20 cm	00384401009702
IGK0018-20S	18 mm	20 cm	00384401009726
IGK0020-20S	20 mm	20 cm	00384401009740
IGK0022-20S	22 mm	20 cm	00384401009764
IGK0024-20S	24 mm	20 cm	00384401009788
IGK0006-40S	6 mm	40 cm	00384401009580
IGK0007-40S	7 mm	40 cm	00384401009603
IGK0008-40S	8 mm	40 cm	00384401009627
IGK0010-40S	10 mm	40 cm	00384401009641
IGK0012-40S	12 mm	40 cm	00384401009672
IGK0014-40S	14 mm	40 cm	00384401009696
IGK0016-40S	16 mm	40 cm	00384401009719
IGK0018-40S	18 mm	40 cm	00384401009733
IGK0020-40S	20 mm	40 cm	00384401009757
IGK0022-40S	22 mm	40 cm	00384401009771
IGK0024-40S	24 mm	40 cm	00384401009795
IGK0006-70S	6 mm	70 cm	00384401009597
IGK0007-70S	7 mm	70 cm	00384401009610
IGK0008-70S	8 mm	70 cm	00384401009634
IGK0010-70S	10 mm	70 cm	00384401009658

INTERGARD Silver Knitted Straight Radially Supported (RS)

Reference	Diameter	Proximal/Distal length	Supported length	Total	Device Identifier (DI)
IGK0006RS20S	6 mm	35 cm/15 cm	20 cm	70 cm	00384401009801
IGK0006RS30S	6 mm	25 cm/15 cm	30 cm	70 cm	00384401009818
IGK0006RS30NGGS	6 mm	25 cm/15 cm	30 cm	70 cm	00384401010432
IGK0006RS45S	6 mm	20 cm/20 cm	45 cm	85 cm	00384401009825
IGK0008RS15S	8 mm	40 cm/15 cm	15 cm	70 cm	00384401010142
IGK0008RS15-40S	8 mm	12,5 cm/12,5 cm	15 cm	40 cm	00384401010159
IGK0008RS20S	8 mm	35 cm/15 cm	20 cm	70 cm	00384401009849
IGK0008RS45S	8 mm	20 cm/20 cm	45 cm	85 cm	00384401009863
IGK0008RS30S	8 mm	25 cm/15 cm	30 cm	70 cm	00384401009856
IGK0008RS60S	8 mm	20 cm/20 cm	60 cm	100 cm	00384401009870
IGK0010RS10-40S	10 mm	15 cm/15 cm	10 cm	40 cm	00384401011354

INTERGARD Silver Knitted Bifurcated

Reference	Diameter	Length	Device Identifier (DI)
IGK1206S	12 x 6 mm	50 cm	00384401009887
IGK1407S	14 x 7 mm	50 cm	00384401009894
IGK1608S	16 x 8 mm	50 cm	00384401009900
IGK1809S	18 x 9 mm	50 cm	00384401009917
IGK2010S	20 x 10 mm	50 cm	00384401009924
IGK2211S	22 x 11 mm	50 cm	00384401009931
IGK2412S	24 x 12 mm	50 cm	00384401009948

INTERGARD Silver Knitted Axillo-bifemoral

Reference	Diameter (Body/Branch)	Supported length (Body/Branch)	Total	Device Identifier (DI)
IGKAX0808S	8 x 8 mm	N/A	100 x 60 cm	00384401103790

INTERGARD Silver Knitted Axillo-bifemoral Radially Supported (RS)

Reference	Diameter (Body/Branch)	Supported length (Body/Branch)	Total	Device Identifier (DI)
IGKAX0808RS45/20S	8 x 8 mm	45 x 20 cm	85 x 55 cm	00384401103813
IGKAX0808RS45/30S	8 x 8 mm	45 x 30 cm	85 x 55 cm	00384401103820
IGKAX0808RS60/30S	8 x 8 mm	60 x 30 cm	100 x 55 cm	00384401103837

2- INTERGARD Silver Knitted Ultrathin

The following codifications are used within this group:

- IGKUT (INTERGARD Knitted Ultrathin)
- RS (Radially Supported)
- S (Silver)

INTERGARD Silver Knitted Ultrathin Straight

Reference	Diameter	Length	Device Identifier (DI)
IGKUT0006-40S	6 mm	40 cm	00384401103622
IGKUT0007-40S	7 mm	40 cm	00384401103639
IGKUT0008-40S	8 mm	40 cm	00384401103646
IGKUT0006-70S	6 mm	70 cm	00384401103660
IGKUT0007-70S	7 mm	70 cm	00384401103677
IGKUT0008-70S	8 mm	70 cm	00384401103684

INTERGARD Silver Knitted Ultrathin Straight Radially Supported (RS)

Reference	Diameter	Proximal/Distal length	Supported length	Total Length	Device Identifier (DI)
IGKUT0006RS20S	6 mm	35 cm/15 cm	20 cm	70 cm	00384401103721
IGKUT0006RS30S	6 mm	25 cm/15 cm	30 cm	70 cm	00384401103738
IGKUT0007RS20S	7 mm	35 cm/15 cm	20 cm	70 cm	00384401103745
IGKUT0007RS30S	7 mm	25 cm/15 cm	30 cm	70 cm	00384401103752
IGKUT0008RS10-40S	8 mm	15 cm/15 cm	10 cm	40 cm	00384401011361
IGKUT0008RS15S	8 mm	40 cm/15 cm	15 cm	70 cm	00384401103783
IGKUT0008RS15-40S	8 mm	12.5 cm/12.5 cm	15 cm	40 cm	00384401103882
IGKUT0008RS20S	8 mm	35 cm/15 cm	20 cm	70 cm	00384401103769
IGKUT0008RS30S	8 mm	25 cm/15 cm	30 cm	70 cm	00384401103776

3- INTERGARD Silver Woven

The following codifications are used within this group:

- IGW (INTERGARD Woven)
- S (Silver)

INTERGARD Silver Woven Straight

Reference	Diameter	Length	Device Identifier (DI)
IGW0012-15S	12 mm	15 cm	00384401009290
IGW0014-15S	14 mm	15 cm	00384401009313
IGW0016-15S	16 mm	15 cm	00384401009337
IGW0018-15S	18 mm	15 cm	00384401009351
IGW0020-15S	20 mm	15 cm	00384401009375
IGW0022-15S	22 mm	15 cm	00384401009399
IGW0024-15S	24 mm	15 cm	00384401009412
IGW0026-15S	26 mm	15 cm	00384401009436
IGW0028-15S	28 mm	15 cm	00384401009450
IGW0030-15S	30 mm	15 cm	00384401009474
IGW0032-15S	32 mm	15 cm	00384401009498
IGW0008-30S	8 mm	30 cm	00384401009276
IGW0010-30S	10 mm	30 cm	00384401009283
IGW0012-30S	12 mm	30 cm	00384401009306
IGW0014-30S	14 mm	30 cm	00384401009320
IGW0016-30S	16 mm	30 cm	00384401009344
IGW0018-30S	18 mm	30 cm	00384401009368
IGW0020-30S	20 mm	30 cm	00384401009382
IGW0022-30S	22 mm	30 cm	00384401009405
IGW0024-30S	24 mm	30 cm	00384401009429
IGW0026-30S	26 mm	30 cm	00384401009443
IGW0028-30S	28 mm	30 cm	00384401009467
IGW0030-30S	30 mm	30 cm	00384401009481
IGW0032-30S	32 mm	30 cm	00384401009504

INTERGARD Silver Woven Bifurcated

Reference	Diameter	Length	Device Identifier (DI)
IGW1407S	14 x 7 mm	50 cm	00384401009535
IGW1608S	16 x 8 mm	50 cm	00384401009542
IGW1809S	18 x 9 mm	50 cm	00384401009559
IGW2010S	20 x 10 mm	50 cm	00384401009566
IGW2211S	22 x 11 mm	50 cm	00384401009573
IGW2412S	24 x 12 mm	50 cm	00384401010296

4- HEMAPATCH Silver Knitted Ultrathin

The following codifications are used within this group:

- HEK (HEMAPATCH Knitted)
- UT (Ultrathin)
- S (Silver)

HEMAPATCH Silver Knitted Ultrathin Patch

Reference	Dimensions	Device Identifier (DI)
HEK10/150UTS (1)	10 x 150 mm	00384401011279
HEK14/75UTS (1)	14 x 75 mm	00384401011262
HEK25/100UTS (1)	25 x 100 mm	00384401011286