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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

Digitally signed by Dubalari Pavel
Date: 2022.10.18 16:31:59 EEST
Reason: MoldSign Signature
Location: Moldova

Date, 2020-06-24

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 103025 0007 Rev. 02

Holder of Certificate: **INTERVASCULAR SAS**
Z.I. Athélia 1
13705 La Ciotat Cedex
FRANCE

Facility(ies): INTERVASCULAR SAS
Z.I. Athélia 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

Report No.: 713186119

Valid from: 2021-07-02
Valid until: 2023-12-31

Date, 2021-07-02

Christoph Dicks
Head of Certification/Notified Body

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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 104153 0004 Rev. 00

Manufacturer: **Atrium Medical Corporation**
40 Continental Blvd
Merrimack NH 03054
USA

Product Category(ies): **Chest drains, thoracic catheters, vascular grafts, peripheral catheters and peripheral vascular stents.**

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.: 72155628

Valid from: 2020-02-05
Valid until: 2024-05-26

Date, 2020-02-03

Christoph Dicks
Head of Certification/Notified Body

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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 104153 0004 Rev. 00

Facility(ies):

Atrium Medical Corporation
40 Continental Blvd, Merrimack NH 03054, USA

.

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 104153 0006 Rev. 00

Certificate Holder: **Atrium Medical Corporation**
40 Continental Blvd
Merrimack NH 03054
USA

Certification Mark:

Scope of Certificate: **Design and Development, Manufacturing and Distribution of Chest Drains, Connectors, Suction Bulbs, Suction Connectors, Tube Pack, Thoracic Catheters, Vascular Grafts, Tunnelers, and Peripheral Vascular Stents for Vascular and Cardiothoracic Surgery**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **05-179-8999**

Effective Date: **2020-12-18**

Expiry Date: **2021-12-17**

Date of Issue: 2020-12-18

(Tina Israel)
Manager, US Certification Body,
Medical and Health Services

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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 104153 0006 Rev. 00

Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):
Atrium Medical Corporation
40 Continental Blvd, Merrimack NH 03054, USA

Facility Scopes:
Design and Development, Manufacturing and Distribution of Chest Drains, Connectors, Suction Bulbs, Suction Connectors, Tube Pack, Thoracic Catheters, Vascular Grafts, Tunnelers, and Peripheral Vascular Stents for Vascular and Cardiothoracic Surgery
DUNS No: 05-179-8999

Date of Issue: 2020-12-18

(Tina Israel)
Manager, US Certification Body,
Medical and Health Services

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Product Service

Add value.
Inspire trust.

To whom it may concern

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
	Dr. Andreas Purde	Andreas.purde@tuvsud.com		2021-08-25	1 of 1

ISO 13485 certification status of Atrium Medical Corporation, Merrimack, NH, USA

Dear Madam or Sir,

The ISO 13485:2016 certificate of Atrium Medical Corporation with number QS2 104153 003 Rev 01 expires on 2021-08-26. The reason why no new certificate could be issued in time are restrictions resulting from the COVID-19 crisis.

Atrium Medical Corporation however is also holding a MDSAP + ISO 13485:2016 certificate with number QS6 104153 006 Rev 00. This certificate covers all ISO 13485:2016 requirements and in addition all MDSAP requirements.

Kind regards

Dr. Andreas Purde
Director
PS-MHS-RBL-1

ePTFE vascular grafts

FLIXENE

Lot : 5; 6

FLIXENE provides a durable vascular access option

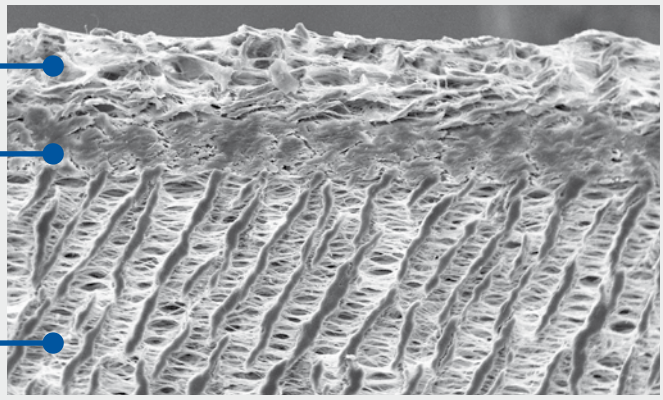
- **Durable Construction**
  Engineered to meet clinical demands
- **Strength and Durability**
  FLIXENE exhibits high radial tensile strength even after simulated needle cannulations[1]
- **Improved Suture Retention**
  FLIXENE offers greater suture retention over Maquet's single-layer ePTFE grafts[1]
- **Published Data**
  Successful early cannulation (24-72 hours) in select patient series[2]

3 Layer ePTFE graft

Large pore surface layer, more receptive to tissue ingrowth

Middle layer, reinforcing wrap for added durability

Small pore base layer, inner graft surface porosity of nominal 20um



1. *Data on file.*
2. *Schild AF, Schuman ES, Noicely K, et al. Early cannulation prosthetic graft (FLIXENE) for arteriovenous access. J Vasc Access. 2011 Jul-Sep;12(3):248-52.*

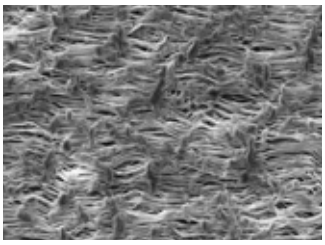
ePTFE vascular grafts

ADVANTA VXT

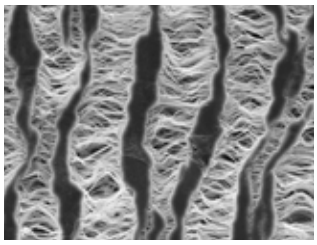
Lot : 5; 6

2-Layer Reinforced Grafts

Experience Maquet's VXT graft technology in your next surgical graft placement. The 2-layer construction makes VXT a strong and durable vascular graft.



VXT has a large pore surface



VXT has an inner surface porosity of nominal 20 µm

Straight

Diameter	Length	Wall Thickness	Helix/ Ring Support	Slider GDS	Reference
4 mm	10 cm	SW	No	No	21276
4 mm	50 cm	SW	No	No	21015
4 mm	70 cm	SW	No	No	21024
5 mm	10 cm	SW	No	No	21277
5 mm	40 cm	SW	No	Yes	22011
5 mm	50 cm	SW	No	Yes	22016
5 mm	70 cm	SW	No	Yes	22025
6 mm	10 cm	SW	No	No	21000
6 mm	10 cm	TW	No	No	21154
6 mm	30 cm	SW	No	No	21007
6 mm	40 cm	SW	No	Yes	22012
6 mm	40 cm	TW	No	Yes	22169
6 mm	50 cm	SW	No	Yes	22017
6 mm	50 cm	TW	No	Yes	22175
6 mm	70 cm	SW	No	Yes	22026
6 mm	70 cm	TW	No	Yes	22185
6 mm	80 cm	TW	No	Yes	22190
7 mm	10 cm	SW	No	No	21001
7 mm	50 cm	SW	No	Yes	22018
7 mm	50 cm	TW	No	Yes	22176
7 mm	70 cm	SW	No	Yes	22027
7 mm	70 cm	TW	No	Yes	22186
8 mm	10 cm	SW	No	No	21002
8 mm	40 cm	SW	No	Yes	22014
8 mm	40 cm	TW	No	Yes	22170
8 mm	50 cm	SW	No	Yes	22019
8 mm	70 cm	SW	No	Yes	22028
8 mm	70 cm	TW	No	Yes	22187
8 mm	80 cm	TW	No	Yes	22192
10 mm	50 cm	SW	No	No	21020
10 mm	70 cm	SW	No	No	21029

Externally supported

Diameter	Length	Wall Thickness	Helix/ Ring Support	Slider GDS	Reference
5 mm	10 cm	SW	Yes	No	21279
5 mm	40 cm	SW	Yes	Yes	22058
5 mm	50 cm	SW	Yes	Yes	22061
5 mm	80 cm	SW	Yes	No	21074
6 mm	40 cm	SW	Yes	Yes	22059
6 mm	45 cm	SW	Yes	Yes	22092
6 mm	50 cm	SW	Yes	Yes	22012
6 mm	50 cm	SW	Yes	Yes	22062
6 mm	50 cm	TW	Yes	Yes	22212
6 mm	70 cm	SW	Yes	Yes	22070
6 mm	70 cm	TW	Yes	Yes	22220
6 mm	80 cm	SW	Yes	Yes	22075
6 mm	80 cm	TW	Yes	Yes	22225
6 mm	100 cm	TW	Yes	Yes	22232
7 mm	50 cm	SW	Yes	Yes	22063
7 mm	50 cm	TW	Yes	Yes	22213
7 mm	70 cm	SW	Yes	Yes	22071
7 mm	70 cm	TW	Yes	Yes	22221
7 mm	80 cm	SW	Yes	Yes	22076
8 mm	40 cm	TW	Yes	Yes	22209
8 mm	50 cm	SW	Yes	Yes	22064
8 mm	50 cm	TW	Yes	Yes	22214
8 mm	70 cm	SW	Yes	Yes	22072
8 mm	70 cm	TW	Yes	Yes	22222
8 mm	80 cm	TW	Yes	Yes	22227
10 mm	80 cm	SW	Yes	No	21078

Trumpet

Diameter	Length	Wall Thickness	Helix/ Ring Support	Slider GDS	Reference
6 mm	40 cm	SW	No	Yes	22280
6 mm	40 cm	SW	Yes	Yes	22279
6 mm	80 cm	TW	Yes	Yes	22286
7 mm	80 cm	TW	Yes	Yes	22287
8 mm	80 cm	TW	Yes	Yes	22288

Tapered

Diameter	Length	Wall Thickness	Helix/ Ring Support	Slider GDS	Reference
4-6mm	45 cm	SW	No	Yes	22114
4-7mm	45 cm	SW	No	Yes	22115
4-7mm	70 cm	SW	No	Yes	22117
4-7mm	45 cm	SW	No	Yes	22297
5-8mm	45 cm	SW	No	Yes	22116
4-6 mm	45 cm	SW	Yes	Yes	22124
4-7mm	45 cm	SW	Yes	Yes	22125
4-7mm	80 cm	TW	Yes	Yes	22266
5-8 mm	80 cm	TW	Yes	Yes	22267

Lot: 8

Hemagard Carotid Patch Knitted

Collagen-coated polyester patch.
Reverse locknit knitting technique.
Water permeability: < 5ml/cm²/min[1]

Questions? Ask us about Hemagard Carotid Patch Knitted

Knitted

Width	Length	Tapered	Reference
6 mm	75 mm	No	HGKTP06/75CP (1)
8 mm	75 mm	No	HGKTP08/75CP (1)
10 mm	75 mm	Yes	HGK10/75CP (1)
12 mm	75 mm	Yes	HGK12/75CP (1)