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

Digitally signed by Ghereg Victor
Date: 2024.07.12 15:25:09 EEST
Reason: MoldSign Signature
Location: Moldova

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

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

TÜV®

Lloyd's Register

Current issue date:	19 September 2020	Original approval(s):
Expiry date:	18 September 2023	ISO 14001 - 19 September 2011
Certificate identity number:	10291430	

Certificate of Approval

This is to certify that the Management System of:

INTERVASCULAR SAS

Z.I Athelia 1, 13705 LA CIOTAT, France

has been approved by Lloyd's Register to the following standards:

ISO 14001:2015

Approval number(s): ISO 14001 – 0033458

The scope of this approval is applicable to:

Manufacture of vascular products.

Daniel Oliva Marcilio de Souza

Area Operations Manager - South Europe

Issued by: LRQA France SAS

for and on behalf of: Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS
001

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.

GETINGE

Lot : 13

Hemacarotid Patch Knitted

Knitted Patches

Material*:

- Collagen-coated polyester patch
- Reverse lock-knit knitting technique
- Magnetic Resonance Safe
- Water permeability : < 5ml/cm²/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