EC Certificate
Full Quality Assurance System

Certificate No.:
13422-2018-CE-CZS-NA-PS Rev. 2.0

Project No.:
PRJC-575486-2017-PRC-CZE

Valid Until:
01 November 2023

This is to certify that the quality system of:

Biosintex S.R.L.
4 Vladiceasca Str.
077168 Snagov
Romania

Digitally signed by Dubalari Pavel
Date: 2021.12.23 16:48:21 EET
Reason: MoldSign Signature
Location: Moldova

For design, production and final product inspection/testing of:

Sterile surgical sutures

Has been assessed with respect to:

The conformity assessment procedure described in Annex II of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 17 October 2019

NORWEGIAN ACCREDITATION

PROD 021
Notified Body No.: 2460

For: DNV GL Presafe AS

Palani Damodharan

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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Project No.: **PRJC-575486-2017-PRC-CZE**

Valid Until: **01 November 2023**

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
	Original Certificate	2018-11-01
1.0	Change of product name	2019-09-11
2.0	**Editorial change** **BICRIL changed to DACRIL** **BICRIL RAPID changed to DACRIL RAPID** **BICRIL 910 changed to DACRIL 910**	**2019-10-17**

Products covered by this Certificate:

Product Description	Product Name	Class
Surgical suture with /without needle	**DACRIL**- Polyglycolic acid multifilament coated absorbable **DACRIL RAPID**- Polyglycolic acid multifilament coated fast absorbable **DACRIL 910** - Poly(glycolide-co-Lactide) (90/10) multifilament coated absorbable **PDO-x** - Polydioxanone monofilament absorbable **MONO-x** - Poly(glycolide-co-caprolactone) (75/25) monofilament absorbable **BIOPRO**- Polypropylene monofilament non-absorbable	III*

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 13464-2018-CE-CZS-NA-PS

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Project No.:
PRJC-575486-2017-PRC-CZE

Valid Until:
01 November 2023

Sites covered by this certificate

Site Name	Address
BIOSINTEX S.R.L.	4 Vladiceasca Str., RO 077168, Snagov, Romania

EC Certificate
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Certificate No.:	Project No.:	Valid Until:
13422-2018-CE-CZS-NA-PS Rev 2.0	**PRJC-575486-2017-PRC-CZE**	**01 November 2023**

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

MANAGEMENT SYSTEM CERTIFICATE

Certificate No.:	Project No.:	Initial Certification Date:	Valid Until:
257642-2018-AQ-CZE-NA-PS rev. 2.0	PRJC-575485-2017-MSC-CZE	11 April 2019	11 April 2022

This is to certify that the management system of:

BIOSINTEX S.R.L.

4 Vladiceasca Str. 077168, Snagov, Ilfov County, Romania

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

DESIGN, DEVELOPMENT, MANUFACTURING AND TRADE OF STERILE SURGICAL SUTURES, WITH/ WITHOUT NEEDLES.

Place and date:
Høvik, 01 February 2021

NORWEGIAN ACCREDITATION
MSYS 018

For:
DNV GL PRESAFE AS

Tone Kolpus

Tone Elise Kolpus

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

EC DESIGN EXAMINATION CERTIFICATE

This is to certify that Lloyd's Register Quality Assurance, a Notified Body under the terms of:
the Medical Devices Directive 93/42/EEC;
the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618;
did (in accordance with Annex II clause 4 of the Directive) undertake an EC Design Examination on the stated products to ensure their conformity with the requirements of the Directive which apply to them. The products identified below were shown to comply.

This certificate is issued to:

MANUFACTURER:	**InterVascular SAS** **Z.I. Athélia 1,** **13705 La Ciotat Cedex** **France**
PRODUCT NAME:	**Collagen Coated Vascular Prostheses and Patches**
PRODUCT DESCRIPTION:	**InterGard Knitted Vascular Prosthesis** **InterGard Knitted Radially Supported Vascular Prosthesis** **InterGard Woven Vascular Prosthesis** **InterGard Aortic Arch Woven Vascular Prosthesis** **InterGard HemaBridge Woven Vascular Prosthesis** **InterGard Knitted UltraThin Vascular Prosthesis** **InterGard Knitted UltraThin Radially Supported Vascular Prosthesis** **Hemagard Knitted Vascular Prosthesis** **Hemagard Knitted Radially Supported Vascular Prosthesis** **Hemagard Knitted UltraThin Vascular Prosthesis** **Hemagard Knitted UltraThin Radially Supported Vascular Prosthesis** **HemaPatch Knitted Vascular Patch** **HemaPatch Woven Vascular Patch** **HemaCarotid Patch Knitted** **HemaCarotid Patch Knitted UltraThin** **Hemagard Knitted Vascular Patch** **Hemagard Carotid Patch Knitted** **Hemagard Carotid Patch Knitted UltraThin** **CardioRoot Woven Vascular Prosthesis**
DESIGN DOSSIER REFERENCE:	**Collagen Coated Vacular Prostheses and Patches rev 4 dated 3 July 2017**

This Certificate is not valid for products, the design or characteristics of which have been varied from those examined. The manufacturer shall notify LRQA of any modification or changes to the products in order to maintain a valid certificate.

Certificate No:	0088/0943962/00036
Original Approval:	21 July 1997
Current Certificate:	1 September 2017
Certificate Expiry:	31 August 2022
LRQA Notified Body Number 0088	David Dennis Issued by: Lloyd's Register Quality Assurance Limited

1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom

EC DESIGN EXAMINATION CERTIFICATE
CERTIFICATE 0088/0943962/00036 SUPPLEMENT

LRQA hereby confirms that the change(s) detailed below have been reviewed in conjunction with the approved Design Dossier and the EC Design Examination remains valid.

This supplement is only valid in association with the EC Design Examination certificate detailed above.

Supplement Number:	Supplement Date:	Details of amendment:
0	20 October 2017	Renewal of certificate on job 1155114

Certificate No: 0088/0943962/00036

Original Approval: 21 July 1997

Current Certificate: 1 September 2017

Certificate Expiry: 31 August 2022

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom

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®

Lot: 43

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)