



# EC Certificate

## Full Quality Assurance System

Certificate No.:  
**13422-2018-CE-CZS-NA-PS Rev. 1.0**

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

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, 11 September 2019**

**For: DNV GL Presafe AS**



**PROD 021**  
**Notified Body No.: 2460**

**Tone Elise Kolpus**

The Certificate has been digitally signed.  
See [www.presafe.com/digital\\_signatures](http://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.

# EC Certificate

## Full Quality Assurance System

Certificate No.:  
**13422-2018-CE-CZS-NA-PS Rev 1.0**

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
<b>1.0</b>	<b>Change of product name</b>	<b>2019-09-11</b>

Products covered by this Certificate:

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

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

### Sites covered by this certificate

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

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**13422-2018-CE-CZS-NA-PS Rev 1.0**

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

Valid Until:  
**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



# EC Design Examination Certificate

Certificate No.:  
**13464-2018-CE-CZS-NA-PS Rev. 1.0**

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

Valid Until:  
**01 November 2023**

This is to certify that:

## **Sterile surgical sutures**

Manufactured by:

### **Biosintex S.R.L.**

4 Vladiceasca Str.  
077168 Snagov  
Romania

Has been assessed with respect to:

## **Examination of the design of the product as described in Annex II section 4 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, 11 September 2019**



**PROD 021**  
**Notified Body No.: 2460**

**For: DNV GL Presafe**

**Tone Elise Kolpus**

The Certificate has been digitally signed.  
See [www.presafe.com/digital\\_signatures](http://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.

# EC Design Examination Certificate

Certificate No.:  
**13464-2018-CE-CZS-NA-PS Rev. 1.0**

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
<b>1.0</b>	<b>Change of product name</b>	<b>2019-09-11</b>

Products covered by this Certificate:

<b>Type of medical device and identification no.:</b> Sterile surgical sutures	<b>Medical Device Class:</b> III
<b>Short description of the Medical Device:</b> Surgical sutures with or without needle.  <b>DACRIL</b> - Polyglycolic acid multifilament coated, absorbable <b>DACRIL RAPID</b> - Polyglycolic acid multifilament coated, fast absorbable <b>DACRIL 910</b> - Poly(glycolide-co-Lactide)(90/10) multifilament coated, absorbable <b>PDO-x</b> - Polydioxanone monofilament, absorbable <b>MONO-x</b> - Poly(glycolide-co-caprolactone) (75/25) monofilament, absorbable <b>BIOPRO</b> - Polypropylene monofilament, non-absorbable  All the sutures are sterilized by Ethylene Oxide.	

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Project No.:  
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Valid Until:  
**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 inform Presafe of any intended change of the products detailed above and Presafe will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

## Conformity declaration and marking of product

This Certificate must be accompanied with a valid EC Certificate Full Quality Assurance System.

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