# 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.

Digitally signed by Ceaicovschi Tudor
Date: 2021.12.04 11:20:48 EET
Reason: MoldSign Signature
Location: Moldova

Place and Date:
**Høvik, 11 September 2019**

NORWEGIAN ACCREDITATION

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

**For: DNV GL Presafe**

Tone Kolpus

**Tone Elise Kolpus**

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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## 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** |

Products covered by this Certificate:

| **Type of medical device and identification no.:** | **Medical Device Class:** |
|---|---|
| Sterile surgical sutures | III |

**Short description of the Medical Device:**

Surgical sutures with or 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

All the sutures are sterilized by Ethylene Oxide.

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## 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