

# EC CERTIFICATE

Number: 2030288CE03

## Full Quality Assurance System

**Directive 93/42/EEC on Medical devices, Annex II excluding (4)**

(Devices in Class IIa, IIb or III)

Manufacturer:

**Polyganics Innovations B.V.**

**Blauwborgje 32  
9747 AC Groningen  
The Netherlands**

For the product category(ies)

**Implantable Bioresorbable sheet to reinforce soft tissue**

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

# 0344

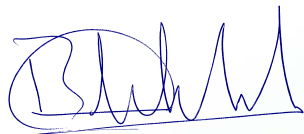
Documents, that form the basis of this certificate:

**Certification Notice 2030288CN, initially dated 24 June 2003  
Addendum, initially dated 21 December 2004**

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 July 2023  
Issued for the first time: 21 December 2004  
Revised: 12 May 2021  
Reissued: 4 August 2018

DEKRA Certification B.V.



**B.T.M. Holtus**  
Managing Director



**J.A. van Vugt**  
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

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# ADDENDUM

Belonging to certificate: 2030288CE03

1/1

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Implantable Bioresorbable sheet to reinforce soft tissue

Issued to:

**Polyganics Innovations B.V.**  
**Blauwborgje 32**  
**9747 AC Groningen**  
**The Netherlands**

This certificate covers the following product(s):

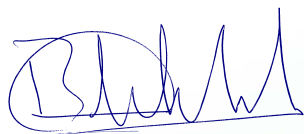
- VIVOSORB

(Polyganics Innovations B.V. uses Polyganics as trade name for the above mentioned products)

Initial date: 21 December 2004

Revision date: 12 May 2021

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of stylized, overlapping loops and lines.

B.T.M. Holtus  
Managing Director

A blue ink signature of J.A. van Vugt, featuring a large, flowing 'J' and 'V' followed by 'A. van Vugt'.

J.A. van Vugt  
Certification Manager

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