

EC CERTIFICATE

Number: 2030288CE02

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)

Bioresorbable devices for peripheral nerve treatment and management

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

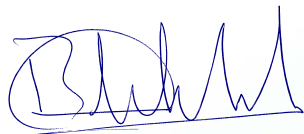
Documents, that form the basis of this certificate:

Certification Notice 2030288CN, initially dated 24 June 2003
Addendum, initially dated 1 April 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: 1 April 2004
Revised: 12 May 2021
Reissued: 1 July 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

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 2030288CE02

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Bioresorbable devices for peripheral nerve treatment and management

Issued to:

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

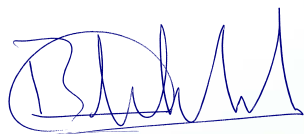
This certificate covers the following product(s):

- NEUROLAC®
- NEUROCAP®

Initial date: 1 April 2004

Revision date: 12 May 2021

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, the Managing Director of DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, the Certification Manager of DEKRA Certification B.V.

J.A. van Vugt
Certification Manager

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