

# CERTIFICATE

Number: 2013959

The management system of the organization(s) and locations mentioned on the addendum belonging to:

**Polyganics Holding B.V.**

**Also trading as Polyganics Innovations B.V.**

**Also trading as Polyganics B.V.**

**Also trading as Polyganics Neurosurgery B.V.**

**Also trading as Polyganics General Surgery B.V.**

**Blauwborgje 32  
9747 AC Groningen  
The Netherlands**

including the implementation meets the requirements of the standard:

## ISO 13485:2016 EN ISO 13485:2016

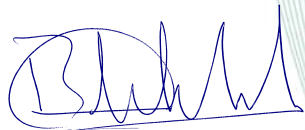
Scope:

Design and Development, manufacture and distribution of sterile, resorbable dressings for the area of ENT, and sterile, resorbable implantable devices for orthopedic/plastic surgery (peripheral nerve repair/tissue separation), neurosurgery (dural sealants), and general surgery (tissue sealants)

Certificate expiry date: 1 July 2027  
Certificate effective date: 1 July 2024  
Certified since: 1 September 2003

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



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



**J.M. McKenzie**  
Certification Manager

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# ADDENDUM

To certificate: 2013959

The management system of the organization(s) and/or location(s) of:

**Polyganics Holding B.V.**  
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**Also trading as Polyganics B.V.**  
**Also trading as Polyganics Neurosurgery B.V.**  
**Also trading as Polyganics General Surgery B.V.**

**Blauwborgje 32**  
**9747 AC Groningen**  
**The Netherlands**

Certified organization(s) and/or locations:

	Different scope
Polyganics B.V. Rozenburglaan 15a 9727 DL Groningen The Netherlands	Design and Development, manufacture and distribution of resorbable material medical devices for the area of ENT.
Polyganics Innovations B.V. Also trading as Polyganics Blauwborgje 32 9747 AC Groningen The Netherlands	Design and Development, manufacture and distribution of resorbable material medical devices for the area of neurosurgery and general surgery.
Polyganics Neurosurgery B.V. Also trading as Polyganics Rozenburglaan 15A 9727 DL Groningen The Netherlands	Design and Development, manufacture and distribution of resorbable material medical devices for the area of neurosurgery.
Polyganics Holding B.V. Rozenburglaan 15A 9727 DL Groningen The Netherlands	Design and Development, manufacture and distribution of resorbable material medical devices for the area of ENT, neurosurgery and general surgery.

# ADDENDUM

To certificate: 2013959

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**Polyganics Holding B.V.**  
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**Also trading as Polyganics B.V.**  
**Also trading as Polyganics Neurosurgery B.V.**  
**Also trading as Polyganics General Surgery B.V.**

**Blauwborgje 32**  
**9747 AC Groningen**  
**The Netherlands**

Polyganics General Surgery B.V. Also trading as Polyganics  
Rozenburglaan 15 a  
9727 DL Groningen  
The Netherlands

Design and development, manufacture and distribution of resorbable material medical devices for the area of general surgery.

Polyganics B.V. Also trading as Polyganics  
Blauwborgje 32  
9747 AC Groningen  
The Netherlands

Design and Development and manufacturing of bioresorbable medical devices for the area of ENT

Addendum expiry date: 1 July 2027  
Addendum effective date: 1 July 2024