

# EC CERTIFICATE

Number: 2119190CE01

## Full Quality Assurance System

**Directive 93/42/EEC on Medical devices, Annex II excluding (4)**  
(Devices in Class IIa, IIb or III)

Manufacturer:

**Amnis Therapeutics Ltd.**

22 Ha'ilan St.  
Or Akiva 3060000  
Israel

For the product category(ies)

**Equine-pericardium covered stents and associated delivery systems**

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 2119190CN, initially dated 6 April 2009**  
**Addendum, initially dated 6 April 2009**

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 October 2019  
Issued for the first time: 6 April 2009  
Revised: 12 November 2015  
Reissued: 1 October 2016

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
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: 2119190CE01

1/1

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Equine-pericardium covered stents and associated delivery systems

Issued to:

**Amnis Therapeutics Ltd.**  
22 Ha'ilan St.  
Or Akiva 3060000  
Israel

This certificate covers the following product(s):

'Over & Under' equine-pericardium covered stents and associated delivery systems  
AneuGraft equine-pericardium covered stents and associated delivery systems

Initial date: 6 April 2009

Revision date: 1 April 2011

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood, written in a cursive style.

drs. G.J. Zoetbrood  
Managing Director

A blue ink signature of ing. A.A.M. Laan, written in a cursive style.

ing. A.A.M. Laan  
Certification Manager

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