EC DESIGN-EXAMINATION CERTIFICATE

Number: 3900504DE01

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:

Amnis Therapeutics ltd.

22 Ha'ilan St.
Or Akiva 3060000
Israel

For the product

Equine Pericardium covered stent and associated delivery system for intraluminal chronic placement where overlay of a cover on the vessel wall is required specifically to be used in the neuro vasculature

Documents, that form the basis of this certificate:

Certification Notice 2119190CN, initially dated 6 April 2009
CE Marking of Conformity 2119190CE01
Addendum, initially dated 4 April 2012

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, 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, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and 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: 4 April 2012
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

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
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 3900504DE01

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Equine Pericardium covered stent and associated delivery system for intraluminal chronic placement where overlay of a cover on the vessel wall is required specifically to be used in the neuro vasculature

Issued to:

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

This certificate covers the following product(s):

- AneuGraft NX

Initial date: 4 April 2012

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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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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ADDENDUM

Belonging to certificate: 2119190CE01

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.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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