EC DESIGN-EXAMINATION CERTIFICATE

Number: 2161507DE04

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

Manufacturer:
ALVIMEDICA TIBBI ÜRÜNLER SAN VE DIS TICARET A.S.
Istanbul Trakya Serbest
Bölgesi Ferhatpasa Mah.
Atatürk Bulv. Manolya Sok.No.7
34540 Çatalca, Istanbul
Turkey

For the product

Cardiovascular and Endovascular Guiding Catheter

Documents, that form the basis of this certificate:

Certification Notice 2161507CN, initially dated 9 April 2013
Addendum, initially dated 23 May 2013

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 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 June 2018
Issued for the first time: 23 May 2013
Reissued: 19 June 2015

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
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ADDENDUM

Belonging to certificate: 2161507DE04

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Cardiovascular and Endovascular Guiding Catheter

Issued to:

ALVIMEDICA TIBBI ÜRÜNLER SAN VE DIS TICARET A.S.
Istanbul Trakya Serbest
Bölgesi Ferhatpasa Mah.
Atatürk Bulv. Manolya Sok.No.7
34540 Çatalca, Istanbul
Turkey

This certificate covers the following product(s):

- Alviguide™ Blue+ Interventional Cardiology Guiding Catheter
- Alguide™ Endovascular Guiding Catheter
- Alviguide™ Cardiovascular Guiding Catheter

Initial date: 23 May 2013
Revision date: 20 March 2014

DEKRA Certification B.V.

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