EC DESIGN-EXAMINATION CERTIFICATE

Number: 2161507DE02

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

Manufacturer:
Alvimedica Tıbbi Ürünler San.ve Dış Tic. A.Ş.
İstanbul Trakya Serbest Bölgesi,
Ferhatpaşa SB Mahallesi
Atatürk Bulvarı No:16 34540
Çatalca-İstanbul
TÜRKİYE

For the product

Bare Metal Stent System for Coronary Use

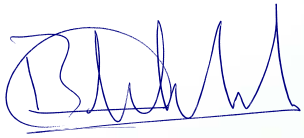
Documents, that form the basis of this certificate:

Certification Notice 2161507CN, initially dated 9 April 2013
CE Marking of Conformity 2161507CE02
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 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 June 2023
Issued for the first time:	23 May 2013
Revised:	5 May 2021
Reissued:	14 June 2018

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director

J.A. van Vugt
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-product-safety.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2161507DE02

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Bare Metal Stent System for Coronary Use

Issued to:

Alvimedica Tıbbi Ürünler San.ve Dış Tic. A.Ş.
İstanbul Trakya Serbest Bölgesi,
Ferhatpaşa SB Mahallesi
Atatürk Bulvarı No:16 34540
Çatalca-İstanbul
TÜRKİYE

This certificate covers the following product(s):

- Ephesos™ II Bare Metal Stent
- Commander™ CoCr Bare Metal Stent
- Constant™ Bare Metal Stent

Initial date: 23 May 2013
Revision date: 5 May 2021

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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EC CERTIFICATE

Number: 2161507CE02

Full Quality Assurance System

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

Manufacturer:

Alvimedica Tıbbi Ürünler San.ve Dış Tic. A.Ş.

İstanbul Trakya Serbest Bölgesi,
Ferhatpaşa SB Mahallesi
Atatürk Bulvarı No:16 34540
Çatalca-İstanbul
TÜRKİYE

For the product category(ies)

Medical devices for cardiovascular interventions applications

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

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 June 2023
Issued for the first time: 23 May 2013
Revised: 25 May 2021
Reissued: 14 June 2018

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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ADDENDUM

Belonging to certificate: 2161507CE02

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Medical devices for cardiovascular interventions applications

Issued to:

Alvimedica Tıbbi Ürünler San.ve Dış Tic. A.Ş.
İstanbul Trakya Serbest Bölgesi,
Ferhatpaşa SB Mahallesi
Atatürk Bulvarı No:16 34540
Çatalca-İstanbul
TÜRKİYE

This certificate covers the following product(s):

- PTCA Balloon Dilatation Catheters
  - Invader™ CTO Balloon Dilatation Catheter;
  - Invader™ PTCA Balloon Dilatation Catheter;
- Bare Metal Stent Systems for Coronary Use
  - Ephesos™ II Bare Metal Stent;
  - Commander™ CoCr Bare Metal Stent;
  - Constant™ Bare Metal Stent;
- Cardiovascular Angiographic Catheters
  - Alvision™ Interventional Cardiology Diagnostic Catheter
- Cardiovascular Guiding Catheters
  - Alviguide™ Blue+ Interventional Cardiology Guiding Catheter

Initial date: 23 May 2013
Revision date: 25 May 2021

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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