

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2161507DE01

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

PTCA Balloon Dilatation Catheters

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 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

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

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ADDENDUM

Belonging to certificate: 2161507DE01

1/1

EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Balloon Dilatation Catheters

Issued to:

ALVIMEDICA TIBBI ÜRÜNLER SAN VE DIS TICARET A.S.

Istanbul Trakya Serbest
Bölgesi Ferhatpasa Mah.
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This certificate covers the following product(s):

- Troya™ Coronary Angioplasty Balloon Catheter
- Invader™ CTO Balloon Dilatation Catheter
- Invader™ PTCA Balloon Dilatation Catheter
- Turquoise™ PTCA Balloon Dilatation Catheter

Initial date: 23 May 2013

Revision date: 20 March 2014

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