

CERTIFICATE

Number: 2161507

The management system of:

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

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

Scope:

Design, development, manufacture and distribution of medical devices for interventional cardiology, including angiographic, diagnostic and guiding catheters.

Third party manufacturing of single use cardiovascular and implantable medical devices.

This certification also includes the location as identified on the addendum belonging to this certificate.

Certificate expiry date: 1 June 2021
Certificate effective date: 14 June 2018
Certified since: 8 July 2013

This certificate is also valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM

To certificate: 2161507

The management system of:

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

List of certified locations

Location	Scope certificate / Activity
Alvimedica Sağlık Ekipmanları Kazancı Yokuşu No. 45 Beyoğlu-Istanbul	Sales and distribution of medical devices for interventional cardiology, including angiographic, diagnostic and guiding catheters.

Initial date: 8 July 2013

Effective date: 14 June 2018